

1C130914

**510(k) Summary
BioFire Diagnostics, Inc.**

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FilmArray Blood Culture Identification (BCID) Panel Kit

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Device Name and Classification:

Trade Name: FilmArray BCID Panel

Regulation Number: 21 CFR 866.3365

Classification Name: Multiplex devices that use DNA hybridization to detect bacteria and their resistance markers

Predicate Device:

K122514 - Nanosphere Verigene[®] Gram-Positive Blood Culture Nucleic Acid Test (BC-BG)

Intended Use:

The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with the FilmArray Instrument. The FilmArray BCID Panel is capable of simultaneous detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance. The BCID assay is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as determined by Gram stain.

The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the FilmArray BCID Panel: *Enterococci*, *Listeria monocytogenes*, commonly

encountered *Staphylococci* (including specific differentiation of *Staphylococcus aureus*), commonly encountered *Streptococci* (with specific differentiation of *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*), *Acinetobacter baumannii*, commonly encountered *Enterobacteriaceae* (including specific differentiation of the *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus*, and *Serratia marcescens*), *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*.

The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (*mecA*), vancomycin (*vanA* and *vanB*), and carbapenems (*bla_{KPC}*) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and carbapenems exist.

FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings. Positive FilmArray results do not rule out co-infection with organisms not included in the FilmArray BCID Panel. FilmArray BCID is not intended to monitor treatment for bacteremia or fungemia.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the FilmArray BCID Panel, and for species determination of some *Staphylococci*, *Enterococci*, *Streptococci*, and *Enterobacteriaceae* that are not specifically identified by the FilmArray BCID Panel assays.

Device Description:

The FilmArray Blood Culture Identification (BCID) Panel is a multiplex nucleic acid test designed to be used with the FilmArray Instrument. The FilmArray BCID pouch contains freeze-dried reagents to perform nucleic acid purification and nested, multiplex PCR with DNA melt analysis. The FilmArray Blood Culture Identification (BCID) Panel simultaneously tests a single positive blood culture sample to provide results for 24 different organisms and organism groups that cause bloodstream infections and three genetic markers that are known to confer antimicrobial resistance (see Table 1).

Table 1. FilmArray BCID Panel Test Results.

Gram-Positive Bacteria	Gram-Negative Bacteria	Yeast
<i>Enterococcus</i>	<i>Acinetobacter baumannii</i>	<i>Candida albicans</i>
<i>Listeria monocytogenes</i>	<i>Enterobacteriaceae</i>	<i>Candida glabrata</i>
<i>Staphylococcus</i>	<i>Enterobacter cloacae</i> complex	<i>Candida krusei</i>
<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Candida parapsilosis</i>
<i>Streptococcus</i>	<i>Klebsiella oxytoca</i>	<i>Candida tropicalis</i>
<i>Streptococcus agalactiae</i>	<i>Klebsiella pneumoniae</i>	Antimicrobial resistance genes
<i>Streptococcus pneumoniae</i>	<i>Proteus</i>	<i>mecA</i> – methicillin resistance

Gram-Positive Bacteria	Gram-Negative Bacteria	Yeast
<i>Streptococcus pyogenes</i>	<i>Serratia marcescens</i>	<i>vanA/B</i> – vancomycin resistance
	<i>Haemophilus influenzae</i>	<i>bla_{KPC}</i> – carbapenem resistance
	<i>Neisseria meningitidis</i> (encapsulated)	
	<i>Pseudomonas aeruginosa</i>	

A test is initiated by loading Hydration Solution and a positive blood culture sample mixed with the provided Sample Buffer into the FilmArray BCID pouch. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared, the FilmArray Software guides the user through the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray Instrument contains a coordinated system of inflatable bladders and seal points, which act on the pouch to control the movement of liquid between the pouch blisters. When a bladder is inflated over a reagent blister, it forces liquid from the blister into connecting channels. Alternatively, when a seal is placed over a connecting channel it acts as a valve to open or close a channel. In addition, electronically controlled pneumatic pistons are positioned over multiple plungers in order to deliver the rehydrated reagents into the blisters at the appropriate times. Two Peltier devices control heating and cooling of the pouch to drive the PCR reactions and the melt curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical lysis and standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, the FilmArray performs a nested multiplex PCR that is executed in two stages. During the first stage, the FilmArray performs a single, large volume, highly multiplexed PCR reaction which includes all primers of the outer primer sets. The products from first stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double stranded DNA binding dye (LC Green[®] Plus+, BioFire Diagnostics). The solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data.

The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism and antimicrobial resistance gene on the panel.

Substantial Equivalence:

The Nanosphere Verigene[®] Gram-Positive Blood Culture Nucleic Acid Test is a qualitative, multiplexed *in vitro* diagnostic test for the simultaneous detection and identification of potentially pathogenic gram-positive bacteria which may cause

bloodstream infection. Table 2 outlines the similarities between the two systems and Table 3 outlines the differences.

Table 2. Similarities Between the FilmArray BCID Panel and the Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test.

Element	FilmArray BCID Panel	Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test
Organisms Detected	<i>Enterococci</i> , <i>Staphylococci</i> (including specific differentiation of <i>Staphylococcus aureus</i>), <i>Streptococci</i> (with specific differentiation of <i>Streptococcus agalactiae</i> , <i>Streptococcus pneumoniae</i> , and <i>Streptococcus pyogenes</i>) and resistance markers <i>mecA</i> , <i>vanA</i> , and <i>vanB</i> .	Same See below for differences
Analyte	DNA	Same
Technological Principles	Multiplex nucleic acid	Same See below for differences
Sample Processing and Purification	Automated by instrument	Same
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Internal procedural/instrument quality controls; Internal Negative Control, Sample processing control, external positive and negative assay controls.
User Complexity	Moderate/Low	Same

Table 3. Differences Between FilmArray Respiratory Panel Test System and the Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test.

Element	FilmArray BCID Panel	Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test
Specimen Types	Positive blood culture samples containing gram-positive, gram-negative bacteria, and/or yeast.	Positive blood culture bottles (unspecified) which contain gram-positive bacteria.
Organisms Detected	Detection of additional targets: <i>Listeria monocytogenes</i> , <i>Acinetobacter baumannii</i> , <i>Enterobacteriaceae</i> (including specific differentiation of <i>Enterobacter cloacae</i> complex species, <i>Escherichia coli</i> , <i>Klebsiella oxytoca</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus</i> , and <i>Serratia marcescens</i>), <i>Haemophilus influenzae</i> , <i>Neisseria meningitidis</i> , <i>Pseudomonas aeruginosa</i> , <i>Candida albicans</i> , <i>Candida glabrata</i> , <i>Candida krusei</i> , <i>Candida parapsilosis</i> , <i>Candida tropicalis</i> , and resistance marker <i>bla_{KPC}</i>	Tests only for gram positive bacteria. Tests for <i>Listeria</i> spp. rather than <i>Listeria monocytogenes</i> . Includes testing for additional <i>Staphylococcus</i> spp.: <i>Staphylococcus epidermidis</i> , <i>Staphylococcus lugdunensis</i> , as well as testing for specific <i>Enterococcus</i> spp.: <i>Enterococcus faecalis</i> , <i>Enterococcus faecium</i> . Includes testing for an additional <i>Streptococcus</i> spp.: <i>Streptococcus anginosus</i> group. Does not include testing for <i>bla_{KPC}</i>

Element	FilmArray BCID Panel	Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test
Technological Principles	Nested multiplex PCR followed by high resolution melting analysis to confirm identity of amplified product.	Qualitative, multiplexed test for the detection of specific nucleic acid targets in a microarray format using capture and mediator oligonucleotides for gold nanoparticle probe-based endpoint detection.
Instrumentation	FilmArray Instrument	Verigene Reader and Processor <i>SP</i>
Time to result	Less than 1 hour	2.5 hours
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Diagnostic Software/Decision Algorithm.

Summary of Performance Data

Clinical Performance

The clinical performance of the FilmArray BCID Panel was established during a two armed clinical study which was conducted at eight U.S. clinical sites over an eight month time period. The study included a prospective residual blood culture arm and a seeded blood culture arm. In the prospective arm, 1635 prospectively-collected residual blood culture samples (pediatric and adult) were initially included in the study. Sixty-seven (67) specimens were excluded from the study. The most common reasons for exclusion were that the specimens were >8 hours past positivity, incomplete reference/comparator data were provided, or the specimen was from a subject who had a previous specimen included in the study. In the seeded culture arm, analytes proven to be of low prevalence in the prospective arm were evaluated by seeding previously characterized isolates into blood culture bottles and incubating until positivity. A total of 716 seeded cultures were initiated for the study. Seventy-seven (77) cultures were excluded from the study. The most common reasons for exclusion were that the specimens were >8 hours past positivity, the seeded culture was not called positive by the automated blood culture system, or the culture was contaminated or inconsistent with the intended seed organism. The final specimen set consisted of 2207 blood cultures (1568 prospective and 639 seeded). All cultures were grown in Becton Dickinson BACTEC™ Plus Aerobic/F Medium. Table 4 provides a summary of demographic information for the 1568 specimens included in the prospective arm of the study.

Table 4. Demographic Summary for Prospective Arm of FilmArray BCID Clinical Evaluation

Prospective Study Specimens	
Total Specimens	1568
Sex	Number of Specimens
Male	917 (58%)
Female	651 (42%)
Age Group	Number of Specimens
≤ 1 year	57 (4%)

Prospective Study Specimens	
Total Specimens	1568
1 - 17 years	92 (6%)
18 - 44 years	281 (18%)
45 - 64 years	583 (37%)
65 - 84 years	442 (28%)
≥ 85 years	113 (7%)

Positive blood cultures (prospective and seeded) were tested with the FilmArray BCID Panel. The performance of FilmArray BCID was evaluated by comparing the FilmArray BCID test result for each panel member with the appropriate comparator/reference methods shown in Table 5.

Table 5. Reference/Comparator Methods used to Assess FilmArray BCID Performance

Test Result	Reference/Comparator Method(s)
All organism detections except <i>Acinetobacter baumannii</i>	Standard manual and automated microbiological/biochemical identification methods ^a
<i>Acinetobacter baumannii</i> detection	Standard manual and automated microbiological/biochemical identification methods Plus 16S PCR with bi-directional sequencing of all <i>A. calcoaceticus-baumannii</i> complex isolates for characterization as <i>A. baumannii</i> or non- <i>A. baumannii</i> ^a
Antimicrobial resistance gene detections in specimens in which an associated organism was detected (<i>mecA</i> from <i>Staphylococcus</i> ; <i>vanA/B</i> from <i>Enterococcus</i> ; KPC from <i>Enterobacteriaceae</i> , <i>Acinetobacter baumannii</i> , and <i>Pseudomonas aeruginosa</i>)	<u>Method 1:</u> PCR with bi-directional sequencing for specific resistance gene direct from blood culture ^b <u>Method 2:</u> PCR with bi-directional sequencing for specific resistance gene from appropriate cultured isolates ^b <u>Informational:</u> Standard manual and automated phenotypic antimicrobial susceptibility testing of appropriate cultured isolates (methicillin resistance, vancomycin resistance, and carbapenem resistance (and/or carbapenemase production) according to current CLSI criteria) ^c

^a Performance of FilmArray BCID detecting all organisms was compared to standard manual and automated microbiological/biochemical identification methods. Additionally isolates identified as being members of the *A. calcoaceticus-baumannii* complex were subjected to 16S PCR and bi-directional sequencing to categorize the isolate as being *A. baumannii* or non-*A. baumannii* for final comparison to the FilmArray BCID *A. baumannii*-specific results. Positive results required a sequencing result of adequate quality to match sequences of *A. baumannii* (or negative result if sequences match non-*A. baumannii* organisms) deposited in the National Center for Biotechnology Information (NCBI) GenBank database (www.ncbi.nlm.nih.gov), with an acceptable E-value. This was required due to the inability of phenotypic identification methods to adequately discriminate between members of the *A. calcoaceticus-baumannii* complex.

^b Performance of FilmArray BCID detecting antimicrobial resistance genes (*mecA*, *vanA/B*, and KPC) was compared to gene-specific PCR tests with bi-directional sequencing. The assays were designed to amplify different sequences than those targeted by FilmArray BCID. Positive results required a sequencing result of adequate quality to match a sequence of the expect gene deposited in the National Center for Biotechnology Information (NCBI) GenBank database (www.ncbi.nlm.nih.gov), with an acceptable E-value.

^c Performance of FilmArray BCID as compared to phenotypic antimicrobial susceptibility testing was performed for informational purposes. The phenotypic methods were performed in accordance with current CLSI criteria.

A total of 2207 blood culture specimens (1568 prospective and 639 seeded) were evaluated in the FilmArray BCID clinical evaluation. Specimens were tested by FilmArray BCID either fresh or from frozen aliquots. A total of 1240 specimens were tested fresh (821 prospective and 419 seeded) and 967 specimens were tested frozen (747 prospective and 220 seeded). Clinical sensitivity or positive percent agreement (PPA) was calculated as 100% x (TP/TP + FN). True positive (TP) indicates that both FilmArray BCID and the reference/comparator method had a positive result for a specific

analyte, and false negative (FN) indicates that the FilmArray BCID result was negative while the reference/comparator method was positive. Clinical specificity or negative percent agreement (NPA) was calculated as $100\% \times (TN/TN + FP)$. True negative (TN) indicates that both FilmArray BCID and the reference/comparator method had a negative result for a specific analyte, and false positive (FP) indicates that the FilmArray BCID result was positive while the reference/comparator method was negative. The exact binomial two-sided 95% confidence interval was calculated. The results are summarized in Tables 6 – 10.

Table 6. FilmArray BCID Clinical Performance Summary – Gram-Positive Organism Results (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

Gram-Positive Bacteria		Sensitivity/PPA ^a			Specificity/NPA ^a		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
<i>Enterococcus</i>	Prospective Fresh	55/55	100	93.5-100	762/766	99.5	98.7-99.9
	Prospective Frozen	43/46	93.5	82.1-98.6	701/701	100	99.5-100
	Seeded Fresh	12/12	100	73.5-100	407/407	100	99.1-100
	Seeded Frozen	17/17	100	80.5-100	203/203	100	98.2-100
	Overall	127/130	97.7	93.4-99.5	2073/2077^b	99.8	99.5-99.9
<i>Listeria monocytogenes</i>	Prospective Fresh	0/0	-	-	821/821	100	99.6-100
	Prospective Frozen	0/0	-	-	747/747	100	99.5-100
	Seeded Fresh	23/23	100	85.2-100	396/396	100	99.1-100
	Seeded Frozen	13/13	100	75.3-100	207/207	100	98.2-100
	Overall	36/36	100	90.3-100	2171/2171	100	99.8-100
<i>Staphylococcus</i>	Prospective Fresh	405/418	96.9	94.7-98.3	401/403	99.5	98.2-99.9
	Prospective Frozen	364/379	96.0	93.6-97.8	359/368	97.6	95.4-98.9
	Seeded Fresh	0/0	-	-	418/419	99.8	98.7-100
	Seeded Frozen	1/1	100	2.5-100	219/219	100	98.3-100
	Overall	770/798^c	96.5	95.0-97.7	1397/1409^c	99.1	98.5-99.6
<i>Staphylococcus aureus</i>	Prospective Fresh	133/136	97.8	93.7-99.5	685/685	100	99.5-100
	Prospective Frozen	120/121	99.2	95.5-100	622/626	99.4	98.4-99.8
	Seeded Fresh	0/0	-	-	419/419	100	99.1-100
	Seeded Frozen	0/0	-	-	220/220	100	98.3-100
	Overall	253/257^d	98.4	96.1-99.6	1946/1950^d	99.8	99.5-99.9
<i>Streptococcus</i>	Prospective Fresh	73/77	94.8	87.2-98.6	740/744	99.5	98.6-99.9
	Prospective Frozen	63/64	98.4	91.6-100	683/683	100	99.5-100
	Seeded Fresh	18/18	100	81.5-100	401/401	100	99.1-100
	Seeded Frozen	44/44	100	92.0-100	175/176	99.4	96.9-100
	Overall	198/203	97.5	94.3-99.2	1999/2004^e	99.8	99.4-99.9
<i>Streptococcus agalactiae</i> (Group B)	Prospective Fresh	8/8	100	63.1-100	813/813	100	99.5-100
	Prospective Frozen	10/10	100	69.2-100	737/737	100	99.5-100
	Seeded Fresh	3/3	100	29.2-100	416/416	100	99.1-100
	Seeded Frozen	15/15	100	78.2-100	205/205	100	98.2-100
	Overall	36/36	100	90.3-100	2171/2171	100	99.8-100
<i>Streptococcus pneumoniae</i>	Prospective Fresh	15/15	100	78.2-100	805/806	99.9	99.3-100
	Prospective Frozen	10/10	100	69.2-100	737/737	100	99.5-100
	Seeded Fresh	4/5	80.0	28.4-99.5	413/414	99.8	98.7-100
	Seeded Frozen	7/7	100	59.0-100	213/213	100	98.3-100
	Overall	36/37	97.3	85.8-99.9	2168/2170	99.9	99.7-100
<i>Streptococcus pyogenes</i> (Group A)	Prospective Fresh	5/5	100	47.8-100	815/816	99.9	99.3-100
	Prospective Frozen	2/2	100	15.8-100	745/745	100	99.5-100
	Seeded Fresh	9/9	100	66.4-100	410/410	100	99.1-100
	Seeded Frozen	22/22	100	84.6-100	198/198	100	98.2-100
	Overall	38/38	100	90.7-100	2168/2169	99.9	99.7-100

^a Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens.

^b 3/4 false positive *Enterococcus* specimens contained *Staphylococcus*; the false positive results may be due to cross-reactivity.

^c Isolates from 16/28 false negative *Staphylococcus* specimens were identified as the newly described species *S. pettenkoferi* by bi-directional sequencing. Bidirectional sequencing confirmed the presence of *Staphylococcus* in 10/12 false positive specimens; 2 were *S. aureus*, 6 were *S. epidermidis*, and 1 was *S. haemolyticus*.

^d Bidirectional sequencing identified 2 isolates from *S. aureus* false negative specimens as *S. hominis* and *S. epidermidis*; they were not *S. aureus*. Bidirectional sequencing confirmed the presence of *S. aureus* in 1/4 false positive specimens. One false positive and one false negative *S. aureus* were in sequentially-tested specimens and may be due to sample mix-up.

^e Bidirectional sequencing confirmed the presence of *S. mitis* in 1/5 false positive *Streptococcus* specimens.

Table 7. FilmArray BCID Clinical Performance Summary – Gram-Negative Organism Results
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification plus 16S
Sequencing for Speciation for *A. baumannii*)

Gram-Negative Bacteria		Sensitivity/PPA ^a			Specificity/NPA ^a		
		TP/TP + FN	%	95% CI	TP/TP + FP	%	95% CI
<i>Acinetobacter baumannii</i>	Prospective Fresh	7/7	100	59.0-100	813/814	99.9	99.3-100
	Prospective Frozen	7/7	100	59.0-100	739/740	99.9	99.2-100
	Seeded Fresh	20/20	100	83.2-100	397/399	99.5	98.2-99.9
	Seeded Frozen	17/17	100	80.5-100	202/203	99.5	97.3-100
	Overall	51/51	100	93.0-100	2151/2156^b	99.8	99.5-99.9
<i>Enterobacteriaceae</i>	Prospective Fresh	153/156	98.1	94.5-99.6	665/665	100	99.4-100
	Prospective Frozen	150/154	97.4	93.5-99.3	589/593	99.3	98.3-99.8
	Seeded Fresh	93/93	100	96.1-100	326/326	100	98.9-100
	Seeded Frozen	94/95	98.9	94.3-100	125/125	100	97.1-100
	Overall	490/498^c	98.4	96.9-99.3	1705/1709^c	99.8	99.4-99.9
<i>Enterobacter cloacae</i> complex	Prospective Fresh	10/11	90.9	58.7-99.8	809/810	99.9	99.3-100
	Prospective Frozen	11/11	100	71.5-100	734/736	99.7	99.0-100
	Seeded Fresh	8/8	100	63.1-100	411/411	100	99.1-100
	Seeded Frozen	9/9	100	66.4-100	211/211	100	98.3-100
	Overall	38/39	97.4	86.5-99.9	2165/2168	99.9	99.6-100
<i>Escherichia coli</i>	Prospective Fresh	77/79	97.5	91.2-99.7	742/742	100	99.5-100
	Prospective Frozen	68/69	98.6	92.2-100	674/678	99.4	98.5-99.8
	Seeded Fresh	4/4	100	39.8-100	414/415	99.8	98.7-100
	Seeded Frozen	1/1	100	2.5-100	219/219	100	98.3-100
	Overall	150/153^d	98	94.4-99.6	2049/2054^d	99.8	99.4-99.9
<i>Klebsiella oxytoca</i>	Prospective Fresh	4/4	100	39.8-100	817/817	100	99.5-100
	Prospective Frozen	1/2	50	1.3-98.7	744/745	99.9	99.3-100
	Seeded Fresh	32/36	88.9	73.9-96.9	383/383	100	99.0-100
	Seeded Frozen	22/22	100	84.6-100	198/198	100	98.2-100
	Overall	59/64^e	92.2	82.7-97.4	2142/2143	99.9	99.7-100
<i>Klebsiella pneumoniae</i>	Prospective Fresh	33/34	97.1	84.7-99.9	786/787	99.9	99.3-100
	Prospective Frozen	35/37	94.6	81.8-99.3	705/710	99.3	98.4-99.8
	Seeded Fresh	13/13	100	75.3-100	403/406	99.3	97.9-99.8
	Seeded Frozen	21/21	100	83.9-100	199/199	100	98.2-100
	Overall	102/105^f	97.1	91.9-99.4	2093/2102^f	99.6	99.2-99.8
<i>Proteus</i>	Prospective Fresh	11/11	100	71.5-100	810/810	100	99.5-100
	Prospective Frozen	11/11	100	71.5-100	736/736	100	99.5-100
	Seeded Fresh	2/2	100	15.8-100	417/417	100	99.1-100
	Seeded Frozen	15/15	100	78.2-100	205/205	100	98.2-100
	Overall	39/39	100	91.0-100	2168/2168	100	99.8-100
<i>Serratia marcescens</i>	Prospective Fresh	14/14	100	76.8-100	807/807	100	99.5-100
	Prospective Frozen	8/8	100	63.1-100	739/739	100	99.5-100
	Seeded Fresh	28/28	100	87.7-100	390/391	99.7	98.6-100
	Seeded Frozen	26/27	96.3	81.0-99.9	193/193	100	98.1-100
	Overall	76/77^g	98.7	93.0-100	2129/2130^g	99.9	99.7-100
<i>Haemophilus influenzae</i>	Prospective Fresh	5/5	100	47.8-100	816/816	100	99.5-100
	Prospective Frozen	3/3	100	29.2-100	744/744	100	99.5-100
	Seeded Fresh	29/29	100	88.1-100	390/390	100	99.1-100
	Seeded Frozen	6/6	100	54.1-100	214/214	100	98.3-100
	Overall	43/43	100	91.8-100	2164/2164	100	99.8-100
<i>Neisseria meningitidis</i>	Prospective Fresh	1/1	100	2.5-100	820/820	100	99.6-100
	Prospective Frozen	0/0	-	-	747/747	100	99.5-100
	Seeded Fresh	30/30	100	88.4-100	389/389	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	36/36	100	90.3-100	2171/2171	100	99.8-100
<i>Pseudomonas aeruginosa</i>	Prospective Fresh	19/19	100	82.4-100	802/802	100	99.5-100
	Prospective Frozen	32/33	97	84.2-99.9	713/714	99.9	99.2-100
	Seeded Fresh	0/0	-	-	419/419	100	99.1-100
	Seeded Frozen	0/0	-	-	220/220	100	98.3-100
	Overall	51/52^h	98.1	89.7-100	2154/2155	99.9	99.7-100

^a Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens

^b Bidirectional sequencing identified isolates from 4 false positive specimens as *A. pitied* (genomospecies 3); this species appears to cross-react with the *A. baumannii* assay. These four isolates were identified as *A. baumannii* by phenotypic methods. 6 other isolates originally identified as

A. baumannii by phenotypic methods were identified by bidirectional sequencing as *A. nosocomialis* (genomospecies 13; 4 isolates), *A. bereziniae*, and *A. radioresistens*; these 6 isolates did not cross-react with the *A. baumannii* assay.

^c One false positive and one false negative *Enterobacteriaceae* were in sequentially-tested specimens and may be due to sample mix-up. One isolate from another false negative specimen, identified as *E. coli* by phenotypic methods, was identified as *Pasteurella*, and not *E. coli*, by bidirectional sequencing.

^d One false positive and one false negative *E. coli* were in sequentially-tested specimens and may be due to sample mix-up.

^e Bidirectional sequencing identified 4/5 isolates from false negative *K. oxytoca* specimens as the closely related species, *Raoultella ornithinolytica*, and not *K. oxytoca*. The misidentification is a known limitation of phenotypic testing methods for this species.

^f The isolate from one false negative *K. pneumoniae* specimen was identified as the closely related organism, *Roultella planticola* and not *K. pneumoniae*. 6/9 false positive *K. pneumoniae* results appear to be due to cross-reactivity with *Enterobacter aerogenes* and *Roultella ornithinolytica* (misidentified as *K. oxytoca* by phenotypic methods).

^g Bidirectional sequencing identified the isolate from the one false negative *S. marcescens* specimen as being in the *S. proteomaculans/grimesii* group and not *S. marcescens*. The one false positive *S. marcescens* result appears to be due to cross-reactivity with *Raoultella ornithinolytica* (misidentified as *K. oxytoca* by phenotypic methods).

^h Bidirectional sequencing identified the isolate from the one false negative *P. aeruginosa* specimen as the closely related species *Pseudomonas stutzeri* and not *P. aeruginosa*.

Table 8. FilmArray BCID Clinical Performance Summary – Yeast Organism Results
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

Yeast		Sensitivity/PPA ^a			Specificity/NPA ^a		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
<i>Candida albicans</i>	Prospective Fresh	12/12	100	73.5-100	808/809	99.9	99.3-100
	Prospective Frozen	4/4	100	39.8-100	740/743	99.6	98.8-99.9
	Seeded Fresh	47/47	100	92.5-100	372/372	100	99.0-100
	Seeded Frozen	1/1	100	2.5-100	219/219	100	98.3-100
	Overall	64/64	100	94.4-100	2139/2143	99.8	99.5-99.9
<i>Candida glabrata</i>	Prospective Fresh	6/6	100	54.1-100	813/815	99.8	99.1-100
	Prospective Frozen	6/6	100	54.1-100	741/741	100	99.5-100
	Seeded Fresh	32/32	100	89.1-100	387/387	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	49/49	100	92.7-100	2156/2158	99.9	99.7-100
<i>Candida krusei</i>	Prospective Fresh	2/2	100	15.8-100	819/819	100	99.6-100
	Prospective Frozen	2/2	100	15.8-100	745/745	100	99.5-100
	Seeded Fresh	28/28	100	87.7-100	391/391	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	37/37	100	90.5-100	2170/2170	100	99.8-100
<i>Candida parapsilosis</i>	Prospective Fresh	3/3	100	29.2-100	818/818	100	99.6-100
	Prospective Frozen	4/4	100	39.8-100	742/743	99.9	99.3-100
	Seeded Fresh	47/49	95.9	86.0-99.5	370/370	100	99.0-100
	Seeded Frozen	5/5	100	47.8-100	214/215	99.5	97.4-100
	Overall	59/61^b	96.7	88.7-99.6	2144/2146	99.9	99.7-100
<i>Candida tropicalis</i>	Prospective Fresh	0/0	-	-	821/821	100	99.6-100
	Prospective Frozen	3/3	100	29.2-100	744/744	100	99.5-100
	Seeded Fresh	31/31	100	88.8-100	388/388	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	39/39	100	91.0-100	2168/2168	100	99.8-100

^a Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens

^b Bidirectional sequencing identified the isolates from the two false negative *C. parapsilosis* specimens as being the closely related species *C. metapsilosis*. This misidentification is a known limitation of phenotypic identification methods.

As the antimicrobial resistance gene results are not reported in the absence of a presumptively associated organism, performance was calculated only for samples in which FilmArray BCID detected an appropriate organism. Performance was calculated separately against the two comparator methods; PCR/sequencing direct from the blood culture specimens and PCR/sequencing from organisms isolated from the blood cultures. When comparing to PCR/sequencing from bacterial isolates, performance was only calculated for specimens in which FilmArray BCID detected an appropriate organism and from which an appropriate organism isolate was obtained (i.e., antimicrobial resistance gene results could be obtained for both methods). The NPA for *mecA* and *vanA/B* are lower when comparing to PCR/sequencing from bacterial isolates than to

PCR/sequencing direct from blood culture primarily due to the reference methods not isolating a resistant clone of an applicable organism. This may be due to heterogeneous resistance within a population of cultured organisms or co-culturing of multiple indistinguishable applicable organisms with different resistance profiles (e.g., culturing a resistant *Staphylococcus* along with a sensitive *Staphylococcus*).

Table 9. FilmArray BCID Clinical Performance Summary – Antimicrobial Resistance Genes (Comparator Method: PCR/Sequencing Direct from Blood Culture).

Antimicrobial Resistance Genes		Sensitivity /PPA ^a			Specificity /NPA ^a		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
<i>mecA</i> - Methicillin Resistance Gene							
<i>mecA</i> All <i>Staphylococcus</i> Detected	Prospective Fresh	253/257	98.4%	96.1-99.6%	147/150	98.0%	94.3-99.6%
	Prospective Frozen	233/237	98.3%	95.7-99.5%	134/136	98.5%	94.8-99.8%
	Seeded Fresh	1/1	100%	n/a	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	488/496	98.4%	96.8-99.3%	281/286	98.3%	96.0-99.4%
<i>mecA</i> <i>Staphylococcus</i> Detected; <i>S. aureus</i> Detected	Prospective Fresh	67/69	97.1%	89.9-99.6%	64/64	100%	94.4-100%
	Prospective Frozen	70/70	100%	94.9-100%	54/54	100%	93.4-100%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	0/0	-	-	0/0	-	-
	Overall	137/139	98.6%	94.9-99.8%	118/118	100%	96.9-100%
<i>mecA</i> <i>Staphylococcus</i> Detected; <i>S. aureus</i> Not Detected	Prospective Fresh	186/188	98.9%	96.2-99.9%	83/86	96.5%	90.1-99.3%
	Prospective Frozen	163/167	97.6%	94.0-99.3%	80/82	97.6%	91.5-99.7%
	Seeded Fresh	1/1	100%	n/a	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	351/357	98.3%	96.4-99.4%	163/168	97.0%	93.2-99.0%
<i>vanA/B</i> - Vancomycin Resistance Genes							
<i>vanA/B</i> <i>Enterococcus</i> Detected	Prospective Fresh	23/23	100%	85.2-100%	36/36	100%	90.3-100%
	Prospective Frozen	13/13	100%	75.3-100%	30/30	100%	88.4-100%
	Seeded Fresh	12/12	100%	73.5-100%	0/0	-	-
	Seeded Frozen	16/16	100%	79.4-100%	1/1	100%	n/a
	Overall	64/64	100%	94.4-100%	67/67	100%	94.6-100%
KPC - Carbapenem Resistance Gene (Carbapenemase)							
KPC <i>Enterobacteriaceae</i> and/or <i>A. baumannii</i> and/or <i>P. aeruginosa</i> Detected	Prospective Fresh	3/3	100%	29.2-100%	177/177	100%	97.9-100%
	Prospective Frozen	3/3	100%	29.2-100%	187/187	100%	98.0-100%
	Seeded Fresh	10/10	100%	69.2-100%	105/105	100%	96.5-100%
	Seeded Frozen	23/23	100%	85.2-100%	89/89	100%	95.9-100%
	Overall	39/39	100%	91.0-100%	558/558	100%	99.3-100%
KPC <i>Enterobacteriaceae</i> Detected	Prospective Fresh	3/3	100%	29.2-100%	150/150	100%	97.6-100%
	Prospective Frozen	3/3	100%	29.2-100%	151/151	100%	97.6-100%
	Seeded Fresh	10/10	100%	69.2-100%	83/83	100%	95.7-100%
	Seeded Frozen	23/23	100%	85.2-100%	71/71	100%	94.9-100%
	Overall	39/39	100%	91.0-100%	455/455	100%	99.2-100%
KPC <i>Enterobacteriaceae</i> Not Detected; <i>A. baumannii</i> and/or <i>P. aeruginosa</i> Detected	Prospective Fresh	0/0	-	-	27/27	100%	87.4-100%
	Prospective Frozen	0/0	-	-	36/36	100%	90.3-100%
	Seeded Fresh	0/0	-	-	22/22	100%	84.6-100%
	Seeded Frozen	0/0	-	-	18/18	100%	81.5-100%
	Overall	0/0	-	-	103/103	100%	96.5-100%

^a Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens.

Table 10. FilmArray BCID Clinical Performance Summary – Antimicrobial Resistance Genes (Comparator Method: PCR/Sequencing of Cultured Isolates)

ANTIMICROBIAL RESISTANCE GENES		Positive Percent Agreement			Negative Percent Agreement ^a		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
<i>mecA</i> - Methicillin Resistance Gene							
<i>mecA</i> All <i>Staphylococcus</i> Detected	Prospective Fresh	234/236	99.2%	97.0-99.9%	149/172	86.7%	80.6-91.3%
	Prospective Frozen	219/222	98.6%	96.1-99.7%	135/151	89.4%	83.4-93.8%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-

ANTIMICROBIAL RESISTANCE GENES		Positive Percent Agreement			Negative Percent Agreement *		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
Overall		454/459	98.9%	97.5-99.6%	284/323	87.9%	83.9-91.3%
<i>mecA</i> <i>Staphylococcus</i> Detected; <i>S. aureus</i> Detected	Prospective Fresh	64/65	98.5%	91.7-100%	65/68	95.6%	87.6-99.1%
	Prospective Frozen	66/66	100%	94.6-100%	54/58	93.1%	83.3-98.1%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	0/0	-	-	0/0	-	-
	Overall	130/131	99.2%	95.8-100%	119/126	94.4%	88.9-97.7%
<i>mecA</i> <i>Staphylococcus</i> Detected; <i>S. aureus</i> Not Detected	Prospective Fresh	170/171	99.4%	96.8-100%	84/104	80.8%	71.9-87.8%
	Prospective Frozen	153/156	98.1%	94.5-99.6%	81/93	87.1%	78.6-93.2%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	324/328	98.8%	96.9-99.7%	165/197	83.8%	77.9-88.6%
<i>vanA/B</i> - Vancomycin Resistance Genes							
<i>vanA/B</i> <i>Enterococcus</i> Detected	Prospective Fresh	20/20	100%	83.2-100%	36/39	92.3%	79.1-98.4%
	Prospective Frozen	12/12	100%	73.5-100%	30/31	96.8%	83.3-99.9%
	Seeded Fresh	12/12	100%	73.5-100%	0/0	-	-
	Seeded Frozen	16/16	100%	79.4-100%	1/1	100%	n/a
	Overall	60/60	100%	94.0-100%	67/71	94.4%	86.2-98.4%
KPC - Carbapenem Resistance Gene (Carbapenemase)							
KPC <i>Enterobacteriaceae</i> and/or <i>A. baumannii</i> and/or <i>P. aeruginosa</i> Detected	Prospective Fresh	3/3	100%	29.2-100%	177/177	100%	97.9-100%
	Prospective Frozen	3/3	100%	29.2-100%	187/187	100%	98.1-100%
	Seeded Fresh	10/10	100%	69.2-100%	105/105	100%	96.5-100%
	Seeded Frozen	23/23	100%	85.2-100%	89/89	100%	95.9-100%
	Overall	39/39	100%	91.0-100%	558/558	100%	99.3-100%
KPC <i>Enterobacteriaceae</i> Detected	Prospective Fresh	3/3	100%	29.2-100%	151/151	100%	97.6-100%
	Prospective Frozen	3/3	100%	29.2-100%	152/152	100%	97.6-100%
	Seeded Fresh	10/10	100%	69.2-100%	83/83	100%	95.7-100%
	Seeded Frozen	23/23	100%	85.2-100%	71/71	100%	94.9-100%
	Overall	39/39	100%	91.0-100%	457/457	100%	99.2-100%
KPC <i>Enterobacteriaceae</i> Not Detected; <i>A. baumannii</i> and/or <i>P. aeruginosa</i> Detected	Prospective Fresh	0/0	-	-	26/26	100%	86.8-100%
	Prospective Frozen	0/0	-	-	35/35	100%	90.0-100%
	Seeded Fresh	0/0	-	-	22/22	100%	84.6-100%
	Seeded Frozen	0/0	-	-	18/18	100%	81.5-100%
	Overall	0/0	-	-	101/101	100%	96.4-100%

* Isolates for 12 *Staphylococci*, 4 *Enterococci*, and 7 *Enterobacteriaceae/A. baumannii/P. aeruginosa* did not grow from the subcultured blood culture and could therefore not be tested with the PCR/bi-directional sequencing comparator method. These blood cultures were considered negative for the antimicrobial resistance genes by comparator method, and FilmArray performance has been calculated as True Negative (when FilmArray is negative for the analyte) or False Positive (when FilmArray is positive for the analyte) for each of these isolates.

Performance of FilmArray BCID as compared to phenotypic antimicrobial susceptibility testing (AST) results was calculated for informational purposes. Results stratified by AST method are presented in Tables 11-13. Some PPA are lower when comparing results from bacterial isolates than to PCR/sequencing direct from blood culture because phenotypic AST testing is capable of detecting antimicrobial resistance due to mechanisms other than acquisition of *mecA*, *vanA/B*, or KPC.

Table 11. *mecA* Performance – Comparison to Phenotypic Antimicrobial Susceptibility Testing (AST) Methods

Note: AST results were not provided for several isolates.

PHENOTYPIC METHODS		Positive Percent Agreement		Negative Percent Agreement	
		TP/TP + FN	% (95%CI)	TN/TN + FP	% (95%CI)
Prospective	Cefoxitin Disc Diffusion	22/22	100%	15/15	100%

All <i>Staphylococcus</i>	Chromogenic Agar	42/46	91.3%	25/32	78.1%
	Automated Antimicrobial Susceptibility Testing	366/380	96.3%	226/262	86.3%
	All Methods	430/448	96.0% (93.7 - 97.6%)	266/309	86.1% (81.7 - 89.7%)
Prospective <i>Staphylococcus</i> , <i>S. aureus</i> Detected	Chromogenic Agar	10/11	90.9%	8/8	100%
	Automated Antimicrobial Susceptibility Testing	117/119	98.3%	108/112	96.4%
	All Methods	127/130	97.7% (93.4 - 99.5%)	116/120	96.7% (91.7 - 99.1%)
Seeded <i>Staphylococcus</i>	Automated Antimicrobial Susceptibility Testing	1/1	100%	0/0	-

Table 12. *vanA/B* Performance – Comparison to Phenotypic Vancomycin AST Methods

PHENOTYPIC METHODS		Positive Percent Agreement TP/TP + FN % (95%CI)		Negative Percent Agreement TN/TN + FP % (95%CI)	
Prospective <i>Enterococcus</i>	Vancomycin Screen Agar	3/3	100%	5/5	100%
	Vancomycin Disc Diffusion	0/1	0.0%	-	-
	Automated Antimicrobial Susceptibility Testing	29/30	96.7%	55/58	94.8%
	All Methods	32/34 ^a	94.1% (80.3 - 99.3%)	60/63	95.2% (86.7 - 99.0%)
Seeded <i>Enterococcus</i>	Vancomycin Disc Diffusion	14/14	100%	1/1	100%
	Vancomycin Screen Agar	14/14	100%	-	-
	All Methods	28/28	100% (87.7 - 100%)	1/1	100% (n/a)
Combined Prospective and Seeded <i>Enterococcus</i>	All Methods	60/62 ^a	96.8% (88.8 - 99.6%)	61/64	95.3% (86.9 - 99.0%)

^aTwo isolates (one *E. gallinarum* and one *E. faecalis*) that were vancomycin resistant by phenotypic AST testing were negative for the *vanA/B* genes by bi-directional sequence analysis.

Table 13. KPC Performance – Comparison to Phenotypic Carbapenem AST Methods

Note: AST results were not provided for several isolates.

Note: *Acinetobacter baumannii* and *Pseudomonas aeruginosa* are commonly resistant to carbapenems due to mechanisms other than acquisition of the KPC gene (*bla_{KPC}*). These bacteria very rarely carry the KPC gene.

PHENOTYPIC METHODS		Positive Percent Agreement TP/ TP + FN % (95%CI)		Negative Percent Agreement TN/ TN + FP % (95%CI)	
Prospective <i>A. baumannii</i>	Automated Antimicrobial Susceptibility Testing	0/10	0%	4/4	100%
Seeded <i>A. baumannii</i>	Meropenem Disc Diffusion	0/30	0%	9/9	100%
<i>A. baumannii</i> – All Methods		0/40	0% (n/a)	13/13	100% (75.3-100%)
Prospective <i>P. aeruginosa</i>	Automated Antimicrobial Susceptibility Testing	0/10	0%	32/32	100%
	Meropenem Disc Diffusion	-	-	6/6	100%
	Meropenem/Ertapenem Disc Diffusion	0/1	0%	2/2	100%
<i>P. aeruginosa</i> – All Methods		0/11	0% (n/a)	40/40	100% (91.2-100%)
Prospective <i>K. pneumoniae</i>	Automated Antimicrobial Susceptibility Testing	6/6	100%	64/64	100%
Seeded <i>K. pneumoniae</i>	Meropenem Disc Diffusion	19/19	100%	1/1	100%
	Modified Hodge Test	11/11	100%	1/1	100%

PHENOTYPIC METHODS		Positive Percent Agreement TP/ TP + FN % (95%CI)		Negative Percent Agreement TN/ TN + FP % (95%CI)	
(Meropenem)					
<i>K. pneumoniae</i> – All Methods		36/36	100% (90.3-100%)	66/66	100% (94.6-100%)
Prospective <i>E. cloacae</i>	Automated Antimicrobial Susceptibility Testing	-	-	22/22	100%
Seeded <i>E. cloacae</i>	Automated Antimicrobial Susceptibility Testing	-	-	3/3	100%
	Meropenem Disc Diffusion	0/1	0%	-	-
	Modified Hodge Test (Meropenem)	2/2	100%	11/11	100%
<i>E. cloacae</i> – All Methods		2/3 *	66.7% (9.4-99.2%)	36/36	100% (90.3-100%)
Prospective <i>E. coli</i>	Automated Antimicrobial Susceptibility Testing	-	-	144/144	100%
Seeded <i>E. coli</i>	Modified Hodge Test (Meropenem)	1/1	100%	4/4	100%
<i>E. coli</i> – All Methods		1/1	100% (n/a)	148/148	100% (97.5-100%)
Prospective <i>P. mirabilis</i>	Automated Antimicrobial Susceptibility Testing	-	-	21/21	100%
Seeded <i>P. mirabilis</i>	Meropenem Disc Diffusion	-	-	4/4	100%
	Modified Hodge Test (Meropenem)	0/1	0%	11/11	100%
<i>P. mirabilis</i> – All Methods		0/1 *	0% (n/a)	36/36	100% (90.3-100%)
Prospective All Other <i>Enterobacteriaceae</i>	Automated Antimicrobial Susceptibility Testing	-	-	43/43	100%
Seeded All Other <i>Enterobacteriaceae</i>	Automated Antimicrobial Susceptibility Testing	-	-	42/42	100%
	Meropenem Disc Diffusion	-	-	13/13	100%
	Modified Hodge Test (Meropenem)	-	-	61/61	100%
All Other <i>Enterobacteriaceae</i> – All Methods		-	-	159/159	100% (97.7-100%)

* Two isolates (one *E. cloacae* and one *P. mirabilis*) that were carbapenem resistant by phenotypic AST testing were negative for the KPC gene by bi-directional sequence analysis.

Table 14. Stratification of *Enterococcus* Clinical Performance by Species
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

<i>Enterococcus</i> species	Positive Agreement	
	Prospective	Seeded
<i>E. avium</i>	2/2 (100%)	-
<i>E. casseliflavus</i>	1/2 (50%)	1/1 (100%)
<i>E. durans</i>	1/1 (100%)	-
<i>E. faecalis</i>	55/56 (98.2%)	8/8 (100%)
<i>E. faecalis</i> + <i>E. faecium</i>	1/1 (100%)	-
<i>E. faecium</i>	36/37 (97.3%)	9/9 (100%)
<i>E. gallinarum</i>	2/2 (100%)	1/1 (100%)
<i>Enterococcus</i> sp. (not speciated)	-	10/10 (100%)
Overall <i>Enterococcus</i>	98/101 (97.0%) 95%CI = 91.6-99.4%	29/29 (100%) 95%CI = 88.1-100%

Table 15. Stratification of *Staphylococcus* Clinical Performance by Species
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

<i>Staphylococcus</i> species	Positive Agreement	
	Prospective	Seeded
<i>S. aureus</i>	256/257 (99.6%)	-
<i>S. auricularis</i>	0/1 (0%)	-
<i>S. capitis</i>	15/17 (88.2%)	-

Staphylococcus species	Positive Agreement	
	Prospective	Seeded
<i>S. capitis</i> + <i>S. epidermidis</i>	1/1 (100%)	-
<i>S. capitis</i> + <i>S. hominis</i>	1/1 (100%)	-
<i>S. capitis</i> + <i>S. lugdunensis</i>	1/1 (100%)	-
<i>S. carnosus</i>	0/1 (0%)	-
<i>S. cohnii</i>	1/1 (100%)	-
<i>S. cohnii</i> + <i>S. hominis</i>	1/1 (100%)	-
<i>S. epidermidis</i>	200/201 (99.5%)	1/1 (100%)
<i>S. epidermidis</i> + <i>S. hominis</i>	4/4 (100%)	-
<i>S. epidermidis</i> + <i>Staphylococcus</i> sp. (not speciated)	2/2 (100%)	-
<i>S. haemolyticus</i>	19/19 (100%)	-
<i>S. haemolyticus</i> + <i>S. hominis</i>	1/1 (100%)	-
<i>S. hominis</i>	65/65 (100%)	-
<i>S. hominis</i> + <i>Staphylococcus</i> sp. (not speciated)	1/1 (100%)	-
<i>S. intermedius</i>	2/2 (100%)	-
<i>S. intermedius</i> + <i>Staphylococcus</i> sp. (not speciated)	1/1 (100%)	-
<i>S. lentus</i>	1/1 (100%)	-
<i>S. lugdunensis</i>	5/5 (100%)	-
<i>S. saprophyticus</i>	2/2 (100%)	-
<i>S. sciuri</i>	0/1 (0%)	-
<i>S. simulans</i>	3/3 (100%)	-
<i>S. warneri</i>	4/5 (80%)	-
<i>Staphylococcus</i> sp. (not speciated) ^a	180/200 (90%)	-
Overall <i>Staphylococcus</i>	769/797 (96.5%) 95%CI = 95.0-97.7%	1/1 (100%) 95%CI = n/a

^a Of the 20 unsequenced staphylococci not detected by FilmArray BCID, 16 were identified as *S. pettenkoferi*, 2 as *S. epidermidis*, 1 as *S. capitis*, and 1 as *S. caprae* by 16S sequence analysis. The 180 unsequenced *Staphylococcus* that were detected by FilmArray BCID were not sequenced.

Table 16. Stratification of *Streptococcus* Clinical Performance by Species
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

Streptococcus species	Positive Agreement	
	Prospective	Seeded
Group A (Pyogenic)		
<i>S. pyogenes</i>	7/7 (100%)	31/31 (100%)
Group B (Pyogenic)		
<i>S. agalactiae</i>	18/18 (100%)	18/18 (100%)
Group C/G (Pyogenic)		
<i>S. canis</i>	1/1 (100%)	-
<i>S. equi/S. dysgalactiae</i>	1/1 (100%)	-
<i>Streptococcus</i> group C	2/2 (100%)	-
<i>Streptococcus</i> group G	2/2 (100%)	-
Group D (Bovis Group)		
<i>S. bovis</i>	3/3 (100%)	-
<i>S. equinus</i>	1/1 (100%)	-
Group F (Anginosus Group)		
<i>S. anginosus</i>	4/4 (100%)	-
<i>S. anginosus</i> group	1/1 (100%)	-
<i>S. intermedius</i>	3/3 (100%)	-
<i>S. constellatus</i>	2/2 (100%)	-
Mitis Group		
<i>S. gordonii</i>	1/1 (100%)	-
<i>S. mitis</i>	8/9 (88.9%)	-
<i>S. mitis</i> + viridans streptococci	1/1 (100%)	-
<i>S. mitis/S. oralis</i>	2/2 (100%)	-
<i>S. mitis/S. oralis</i> + viridans streptococci	1/1 (100%)	-
<i>S. oralis</i>	5/5 (100%)	-
<i>S. parasanguinis</i>	1/1 (100%)	-
<i>S. parasanguinis</i> + viridans streptococci	1/1 (100%)	-
<i>S. pneumoniae</i>	25/25 (100%)	12/12 (100%)
<i>S. sanguinis</i>	2/2 (100%)	-

<i>Streptococcus</i> species	Positive Agreement	
	Prospective	Seeded
Salivarius Group		
<i>S. salivarius</i>	1/2 (50%)	-
<i>S. salivarius</i> + <i>S. sanguinis</i> group	1/1 (100%)	-
Other		
<i>S. vestibularis</i>	1/1 (100%)	-
Viridans streptococci (not further speciated)	40/43 (93.0%)	1/1 (100%)
<i>Streptococcus</i> sp. (not speciated)	1/1 (100%)	-
Overall <i>Streptococcus</i>	136/141 (96.5%) 95%CI = 91.9-98.8%	62/62 (100%) 95%CI = 94.2-100%

**Table 17. Stratification of *Enterobacteriaceae* Clinical Performance by Genus/Species.
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)**

<i>Enterobacteriaceae</i> genus/species	Positive Agreement	
	Prospective	Seeded
<i>Citrobacter freundii</i>	2/2 (100%)	-
<i>Citrobacter freundii</i> + <i>Escherichia coli</i>	1/1 (100%)	-
<i>Citrobacter koseri</i>	1/2 (50%)	-
<i>Enterobacter aerogenes</i>	5/5 (100%)	2/2 (100%)
<i>Enterobacter aerogenes</i> + <i>Klebsiella oxytoca</i>	1/1 (100%)	-
<i>Enterobacter cloacae</i>	19/19 (100%)	17/17 (100%)
<i>Enterobacter cloacae</i> complex	3/3 (100%)	-
<i>Enterobacter gergoviae</i>	1/1 (100%)	-
<i>Enterobacter sakasaki</i>	1/1 (100%)	-
<i>Enterobacter</i> sp.	1/1 (100%)	-
<i>Escherichia coli</i>	141/144 (98%)	5/5 (100%)
<i>Escherichia coli</i> + <i>Klebsiella pneumoniae</i>	2/2 (100%)	-
<i>Escherichia coli</i> + <i>Providencia stuartii</i> ^a	1/1 (100%)	-
<i>Escherichia hermannii</i>	1/1 (100%)	-
<i>Klebsiella oxytoca</i>	5/5 (100%)	58/58 (100%)
<i>Klebsiella pneumoniae</i>	67/68 (99%)	34/34 (100%)
<i>Klebsiella pneumoniae</i> + <i>Pantoea agglomerans</i>	1/1 (100%)	-
<i>Leclercia adacarboxylata</i>	1/1 (100%)	-
<i>Morganella morganii</i> ^b + <i>Proteus mirabilis</i>	1/1 (100%)	-
<i>Pantoea agglomerans</i>	1/1 (100%)	-
<i>Pantoea</i> sp.	0/2 (0%)	-
<i>Proteus mirabilis</i>	21/21 (100%)	15/15 (100%)
<i>Proteus vulgaris</i>	-	2/2 (100%)
<i>Salmonella</i> group B	1/1 (100%)	-
<i>Salmonella</i> group C	1/1 (100%)	-
<i>Salmonella</i> sp.	1/1 (100%)	-
<i>Salmonella typhi</i>	1/1 (100%)	-
<i>Serratia marcescens</i>	22/22 (100%)	54/55 (98%)
Overall <i>Enterobacteriaceae</i>	303/310 (97.7%) 95%CI = 95.4-99.1%	187/188 (99.5%) 95%CI = 97.1-100%

^a FilmArray BCID does not detect *Providencia stuartii*; the positive *Enterobacteriaceae* result is likely due to the presence of *Escherichia coli* in the blood culture.

^b FilmArray BCID does not detect *Morganella morganii*; the positive *Enterobacteriaceae* result is likely due to the presence of *Proteus mirabilis* in the blood culture.

**Table 18. Stratification of *Proteus* Clinical Performance by Species.
(Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)**

<i>Proteus</i> species	Positive Agreement	
	Prospective	Seeded
<i>Proteus mirabilis</i>	22/22 (100%)	15/15 (100%)
<i>Proteus vulgaris</i>	-	2/2 (100%)

Overall Proteus	22/22 (100%) 95%CI = 84.6-100%	17/17 (100%) 95%CI = 80.5-100%
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FilmArray BCID reported a total of 81 prospective specimens with discernible multiple organism detections (5.2% of all prospective specimens; 81/1568). The majority of multiple detections (74/81; 91.3%) contained two discernible organisms, while 6.2% (5/81) contained three discernible organisms, and 2.5% (2/81) contained four discernible organisms. The most prevalent multiple detection was *Enterococcus* with *Staphylococcus* (*S. aureus* not detected) (1.3% of all specimens; 20/1568). Out of the 81 polymicrobial specimens, 29 contained one or more analytes that had not been detected with the reference/comparator methods, i.e., discrepant result.

Table 19. Discernible Multiple Detection Combinations as Determined by FilmArray BCID

Distinct Multiple Detection Combinations as Determined by FilmArray BCID				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Organism Not Detected by Reference Method)
Organism 1 Results	Organism 2 Results	Organism 3 Results	Organism 4 Results			
<i>Enterobacter cloacae</i> complex, <i>Enterobacteriaceae</i>	<i>Escherichia coli</i> , <i>Enterobacteriaceae</i>	<i>Klebsiella oxytoca</i> , <i>Enterobacteriaceae</i>	<i>Klebsiella pneumoniae</i> , <i>Enterobacteriaceae</i>	1	1	<i>E. cloacae</i> , <i>E. coli</i> , <i>K. oxytoca</i>
<i>Candida albicans</i>	<i>Candida glabrata</i>	<i>Staphylococcus</i>	<i>Streptococcus</i>	1	1	<i>C. albicans</i>
<i>Candida albicans</i>	<i>Candida parapsilosis</i>	<i>Enterococcus</i>		1	1	<i>C. parapsilosis</i>
<i>Enterococcus</i>	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>		1	0	
<i>Enterococcus</i>	<i>Proteus</i> , <i>Enterobacteriaceae</i>	<i>Staphylococcus</i>		1	0	
<i>Enterococcus</i>	<i>Staphylococcus</i>	<i>Streptococcus</i>		1	1	<i>Streptococcus</i>
<i>Candida albicans</i>	<i>Staphylococcus</i>	<i>Streptococcus</i>		1	0	
<i>Staphylococcus</i>	<i>Streptococcus agalactiae</i> , <i>Streptococcus</i>			1	0	
<i>Proteus</i> , <i>Enterobacteriaceae</i>	<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>			1	1	<i>Staphylococcus</i> , <i>S. aureus</i>
<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>	<i>Streptococcus agalactiae</i> , <i>Streptococcus</i>			1	0	
<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>	<i>Streptococcus pneumoniae</i> , <i>Streptococcus</i>			1	1	<i>Streptococcus</i> , <i>S. pneumoniae</i>
<i>Escherichia coli</i> , <i>Enterobacteriaceae</i>	<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>			3	0	
<i>Enterococcus</i>	<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>			3	1	<i>Staphylococcus</i> , <i>S. aureus</i>
<i>Candida albicans</i>	<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>			1	1	<i>C. albicans</i>
<i>Acinetobacter baumannii</i>	<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>			1	0	
<i>Staphylococcus aureus</i> , <i>Staphylococcus</i>	<i>Pseudomonas aeruginosa</i>			1	1	<i>P. aeruginosa</i>
<i>Staphylococcus aureus</i>	<i>Streptococcus</i>			4	0	

Distinct Multiple Detection Combinations as Determined by FilmArray BCID				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Organism Not Detected by Reference Method)
Organism 1 Results	Organism 2 Results	Organism 3 Results	Organism 4 Results			
<i>Staphylococcus</i>						
<i>Enterococcus</i>	<i>Escherichia coli</i> , <i>Enterobacteriaceae</i>			1	1	<i>Enterobacteriaceae</i> , <i>E. coli</i>
<i>Acinetobacter baumannii</i>	<i>Klebsiella pneumoniae</i> , <i>Enterobacteriaceae</i>			2	1	<i>A. baumannii</i>
<i>Enterobacter cloacae</i> complex	<i>Klebsiella pneumoniae</i> , <i>Enterobacteriaceae</i>			1	1	<i>E. cloacae</i> complex
<i>Klebsiella pneumoniae</i> , <i>Enterobacteriaceae</i>	<i>Enterococcus</i>			3	1	<i>K. pneumoniae</i> , <i>Enteric</i>
<i>Klebsiella pneumoniae</i> , <i>Enterobacteriaceae</i>	<i>Escherichia coli</i> , <i>Enterobacteriaceae</i>			5	3	<i>E. coli</i> , <i>K. pneumoniae</i> (2)
<i>Candida glabrata</i>	<i>Proteus</i> , <i>Enterobacteriaceae</i>			1	1	<i>C. glabrata</i>
<i>Proteus</i> , <i>Enterobacteriaceae</i>	<i>Enterococcus</i>			1	1	
<i>Enterococcus</i>	<i>Staphylococcus</i>			20	6	<i>Staphylococcus</i> (3), <i>Enterococcus</i> (3)
<i>Staphylococcus</i>	<i>Pseudomonas aeruginosa</i>			1	1	<i>Staphylococcus</i>
<i>Escherichia coli</i> , <i>Enterobacteriaceae</i>	<i>Streptococcus</i>			2	1	<i>Streptococcus</i>
<i>Klebsiella pneumoniae</i> , <i>Enterobacteriaceae</i>	<i>Streptococcus</i>			1	0	
<i>Staphylococcus</i>	<i>Streptococcus</i>			7	0	
<i>Candida albicans</i>	<i>Enterococcus</i>			2	0	
<i>Candida krusei</i>	<i>Enterococcus</i>			1	0	
<i>Candida glabrata</i>	<i>Enterococcus</i>			1	0	
<i>Enterococcus</i>	<i>Staphylococcus</i>			1	0	
<i>Candida albicans</i>	<i>Candida glabrata</i>			1	1	<i>C. glabrata</i>
<i>Candida albicans</i>	<i>Enterococcus</i>			1	1	<i>C. albicans</i>
<i>Enterobacteriaceae</i>	<i>Enterococcus</i>			1	0	
<i>Acinetobacter baumannii</i>	<i>Pseudomonas aeruginosa</i>			2	0	
<i>Enterobacteriaceae</i>	<i>Pseudomonas aeruginosa</i>			1	0	
<i>Enterobacteriaceae</i>	<i>Staphylococcus</i>			1	1	<i>Staphylococcus</i>
Total Specimens with Multiple Detections				81	29	

Table 20. Additional Specimens with Multiple Isolates Identified by Reference/Comparator Methods

Note: Organisms shaded gray are not targeted by FilmArray BCID (i.e., off-panel organisms). This list does not include multiple detection combinations already represented in the previous table of FilmArray BCID multiple detections.

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	Isolate 2	Isolate 3	Isolate 4			
<i>Aeromonas sobria</i>	<i>Pantoea agglomerans</i>	<i>Pantoea agglomerans</i>	<i>Pseudomonas aeruginosa</i>	1	0	
<i>Enterococcus faecalis</i>	<i>Flavobacterium</i> species	<i>Klebsiella pneumoniae</i>	<i>Staphylococcus</i> species	1	1	<i>Staphylococcus</i>
<i>Klebsiella pneumoniae</i>	<i>Staphylococcus</i> species	<i>Staphylococcus</i> species	Viridans streptococci	1	1	<i>Staphylococcus</i> , <i>Streptococcus</i>
<i>Neisseria</i> species	Viridans streptococci	Viridans streptococci	Viridans streptococci	1	0	
<i>Acinetobacter lwoffii</i>	<i>Corynebacterium</i> species	<i>Staphylococcus epidermidis</i>		1	0	
<i>Corynebacterium</i> species	<i>Staphylococcus aureus</i>	<i>Streptococcus oralis</i>		1	0	
<i>Enterococcus casseliflavus</i>	<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>		1	1	<i>Enterococcus</i>
<i>Klebsiella pneumoniae</i>	<i>Klebsiella pneumoniae</i>	<i>Streptococcus mitis/oralis</i>		1	0	
<i>Pantoea</i> species	<i>Staphylococcus intermedius</i>	<i>Staphylococcus</i> species		1	1	<i>Enterobacteriaceae</i>
<i>Staphylococcus aureus</i>	<i>Staphylococcus haemolyticus</i>	<i>Streptococcus parasanguis</i>		1	0	
<i>Staphylococcus capitis</i>	<i>Staphylococcus epidermidis</i>	<i>Staphylococcus lugdunensis</i>		1	0	
<i>Streptococcus mitis/oralis</i>	Viridans streptococci	Viridans streptococci		1	0	
Viridans streptococci	Viridans streptococci	Viridans streptococci		1	0	
<i>Abiotrophia defectiva</i>	<i>Staphylococcus</i> species			1	1	<i>Staphylococcus</i>
<i>Acinetobacter baumannii</i> (seq. = <i>A. nosocomialis/calcoaceticus</i>)	<i>Acinetobacter baumannii</i> (seq. = <i>A. nosocomialis/calcoaceticus</i>)			1	0	
<i>Acinetobacter lwoffii</i>	<i>Klebsiella pneumoniae</i>			1	0	
<i>Acinetobacter lwoffii</i>	Viridans streptococci			1	1	<i>Streptococcus</i>
<i>Acinetobacter lwoffii</i>	<i>Staphylococcus</i> species			1	1	<i>Staphylococcus</i>
<i>Aerococcus viridans</i>	<i>Klebsiella pneumoniae</i>			1	1	<i>K. pneumoniae</i> , <i>Enterobacteriaceae</i>
<i>Aerococcus</i> species	<i>Staphylococcus epidermidis</i>			1	1	<i>Staphylococcus</i>
<i>Bacillus pumilus</i>	<i>Pseudomonas fluorescens/putida</i>			1	0	
<i>Brevundimonas diminuta</i>	<i>Weeksella virosa</i>			1	0	
<i>Candida parapsilosis</i>	<i>Kocuria kristinae</i>			1	0	
<i>Citrobacter freundii</i>	<i>Escherichia coli</i>			1	0	
<i>Citrobacter koseri</i>	<i>Enterococcus faecium</i>			1	0	
<i>Corynebacterium jeikeium</i>	<i>Corynebacterium</i> species			1	0	
<i>Corynebacterium</i> species	<i>Corynebacterium</i> species			1	0	
<i>Corynebacterium</i> species	<i>Enterococcus faecalis</i>			1	0	
<i>Corynebacterium</i> species	<i>Micrococcus</i> species			1	0	
<i>Corynebacterium</i> species	<i>Staphylococcus aureus</i>			2	0	
<i>Corynebacterium</i> species	<i>Staphylococcus haemolyticus</i>			2	0	
<i>Corynebacterium</i> species	<i>Staphylococcus hominis</i>			2	0	
<i>Corynebacterium</i> species	<i>Staphylococcus</i> species			3	1	<i>Staphylococcus</i>
Diphtheroids	<i>Staphylococcus</i> species			1	0	

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	Isolate 2	Isolate 3	Isolate 4			
<i>Enterobacter aerogenes</i>	<i>Klebsiella oxytoca</i>			1	0	
<i>Enterococcus faecalis</i>	<i>Enterococcus faecium</i>			1	0	
<i>Enterococcus faecalis</i>	<i>Stenotrophomonas maltophilia</i>			1	0	
<i>Enterococcus faecalis</i>	Viridans streptococci			1	1	<i>Enterococcus</i>
<i>Enterococcus faecium</i>	<i>Enterococcus faecium</i>			1	0	
<i>Escherichia coli</i>	<i>Escherichia coli</i>			3	0	
<i>Escherichia coli</i>	<i>Pasteurella multocida</i>			1	1	<i>E. coli</i> , <i>Enterobacteriaceae</i>
<i>Escherichia coli</i>	<i>Providencia stuartii</i>			1	0	
<i>Escherichia coli</i>	<i>Stenotrophomonas maltophilia</i>			1	0	
<i>Haemophilus influenzae</i>	<i>Moraxella catarrhalis</i>			1	0	
<i>Klebsiella pneumoniae</i>	<i>Pantoea agglomerans</i>			1	1	<i>K. pneumoniae</i>
<i>Lactobacillus acidophilus</i>	<i>Streptococcus</i> species			1	0	
<i>Micrococcus</i> species	<i>Staphylococcus epidermidis</i>			1	0	
<i>Morganella morganii</i>	<i>Proteus mirabilis</i>			1	0	
<i>Neisseria</i> species	<i>Staphylococcus hominis</i>			1	0	
<i>Rhodococcus</i> species	<i>Staphylococcus warneri</i>			1	1	<i>Staphylococcus</i>
<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i>			2	0	
<i>Staphylococcus aureus</i>	<i>Staphylococcus caprae</i>			1	0	
<i>Staphylococcus aureus</i>	<i>Staphylococcus</i> species			2	0	
<i>Staphylococcus aureus</i>	<i>Streptococcus salivarius</i>			1	1	<i>Streptococcus</i>
<i>Staphylococcus capitis</i>	<i>Staphylococcus capitis</i>			1	0	
<i>Staphylococcus capitis</i>	<i>Staphylococcus epidermidis</i>			1	0	
<i>Staphylococcus capitis</i>	<i>Staphylococcus hominis</i>			1	0	
<i>Staphylococcus capitis</i>	<i>Streptococcus pneumoniae</i>			1	1	<i>Staphylococcus</i>
<i>Staphylococcus cohnii</i>	<i>Staphylococcus hominis</i>			1	0	
<i>Staphylococcus epidermidis</i>	<i>Staphylococcus hominis</i>			4	0	
<i>Staphylococcus epidermidis</i>	<i>Staphylococcus</i> species			2	0	
<i>Staphylococcus haemolyticus</i>	<i>Staphylococcus hominis</i>			1	0	
<i>Staphylococcus hominis</i>	<i>Staphylococcus hominis</i>			1	0	
<i>Staphylococcus hominis</i>	<i>Staphylococcus</i> species			1	0	
<i>Staphylococcus</i> species	<i>Staphylococcus</i> species			3	0	
<i>Staphylococcus</i> species	<i>Stenotrophomonas maltophilia</i>			1	0	
<i>Streptococcus parasanguinis</i>	Viridans streptococci			1	0	
<i>Streptococcus salivarius</i>	<i>Streptococcus sanguis</i> group			1	0	
Viridans streptococci	<i>Streptococcus mitis</i>			1	0	

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	Isolate 2	Isolate 3	Isolate 4			
Viridans streptococci	Viridans streptococci			3	0	
Total				86	16	

The reference method detected 201 off-panel organism isolates (i.e., those not targeted by FilmArray BCID) from the 1568 prospective cultures. The majority of these isolates belong to groups of organisms commonly considered to be blood culture contaminants (49 *Corynebacterium*/Diphtheroids, 33 *Bacillus* sp., and 27 *Micrococcus* sp., among others). Occurrence of off-panel organisms in the prospective arm of the clinical evaluation is presented in Table 21.

Table 21. Occurrence of Off-Panel Organisms as Determined by Reference/Comparator Methods

Off-Panel Organism	Number Identified	Off-Panel Organism	Number Identified
<i>Abiotrophia</i> sp. or <i>Granulicatella</i> sp. (formerly nutritionally-deficient Streptococci)	7	<i>Flavobacterium</i> species	1
<i>Achromobacter xylosoxidans</i>	1	<i>Fusarium</i> species	1
<i>Acinetobacter</i> sp. (not <i>A. baumannii</i>)	23	<i>Kocuria kristinae</i>	1
<i>Actinomyces odontolyticus</i>	2	<i>Lactobacillus acidophilus</i>	1
<i>Actinomyces</i> species	1	<i>Lactobacillus</i> species	2
<i>Aerococcus</i> species	1	<i>Micrococcus luteus</i>	1
<i>Aerococcus viridans</i>	2	<i>Micrococcus luteus/hylae</i>	1
<i>Aeromonas sobria</i>	1	<i>Micrococcus</i> species	25
<i>Bacillus cereus</i>	19	<i>Moraxella catarrhalis</i>	1
<i>Bacillus pumilus</i>	1	<i>Moraxella osloensis</i>	1
<i>Bacillus</i> species	13	<i>Moraxella</i> species	1
<i>Brevibacterium</i> species	1	<i>Mycobacterium fortuitum</i> complex	1
<i>Brevibacterium ensei</i>	1	<i>Mycobacterium</i> species	1
<i>Brevundimonas diminuta</i>	1	<i>Neisseria</i> species	2
<i>Brevundimonas vesicularis</i>	1	<i>Paenibacillus</i> species	1
<i>Burkholderia cepacia</i> complex	2	<i>Pasteurella multocida</i>	2
<i>Candida kefyr</i>	1	<i>Pasteurella</i> species	1
<i>Capnocytophaga</i> species	1	<i>Propionibacterium</i> species	1
<i>Chryseobacterium meningosepticum</i> (<i>Elizabethkingia</i> / <i>Flavobacterium</i>)	1	<i>Pseudomonas fluorescens/putida</i>	2
<i>Chryseobacterium indologenes</i>	1	<i>Pseudomonas</i> species	3
<i>Chryseomonas luteola</i>	1	<i>Rhizobium radiobacter</i>	2
<i>Corynebacterium jeikeium</i>	1	<i>Rothia (Stomatococcus) mucilaginosus</i>	4
<i>Corynebacterium mucifaciens</i>	1	<i>Sphingomonas mucosissima</i>	1
<i>Corynebacterium</i> species/Diphtheroids	47	<i>Stenotrophomonas maltophilia</i>	10
<i>Cryptococcus neoformans</i>	2	<i>Weeksella virosa</i>	1

Selected Analytic Studies

Growth and Detection

A study was performed to establish the range of expected organism concentrations in blood cultures that would be tested with the FilmArray BCID Panel from the time of positivity up to eight hours after positivity. All organism growth and testing was performed using seeded blood culture bottles (BACTEC™ Plus Aerobic/F Medium incubated in the BACTEC™ 9050 continuously monitoring blood culture instrument). Each microorganism was mixed with human whole blood and seeded directly into blood culture bottles for growth. At the time of positivity (and/or eight hours after positivity), the blood culture was removed from the instrument for plate enumeration (determination of CFU/mL) and FilmArray BCID testing. Three independent positive cultures (bottles) were evaluated for each organism at each time point and FilmArray testing was performed in triplicate for each bottle.

Table 22 summarizes the concentration of organism (CFU/mL) determined for a representative panel of 30 isolates. The number and percent of correct positive BCID Panel test results is provided for each isolate and overall (% Detected). A correct result means that both the correct organism and antimicrobial resistance gene (where applicable) were detected in the sample.

Table 22. Summary of Organism Concentration (CFU/mL) in Positive Blood Cultures and Correct Detection of Organisms in Positive Blood Cultures by the FilmArray BCID Panel

Species/Isolate(s) Tested	At Positivity			8 Hours After Positivity		
	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)
Gram-Positive Bacteria						
<i>Enterococcus faecalis</i> [vanB+] JMI 368	4.60E+08 1.80E+08 2.62E+08	3.01E+08	9/9 (100%)	7.25E+08 8.90E+08 1.07E+09	8.95E+08	9/9 (100%)
<i>Enterococcus faecium</i> [vanA+] JMI 475	1.47E+08 1.53E+08 1.59E+08	1.53E+08	9/9 (100%)	2.23E+08 1.64E+08 1.55E+08	1.81E+08	9/9 (100%)
<i>Enterococcus hirae</i> ATCC 49135	1.26E+08 2.76E+08 3.25E+08	2.42E+08	9/9 (100%)	8.00E+08 6.60E+08 7.20E+08	7.27E+08	9/9 (100%)
<i>Listeria monocytogenes</i> CDC F2380 (ATCC 43256)	4.50E+08 1.22E+09 1.18E+09	9.50E+08	9/9 (100%)	1.76E+09 2.31E+09 1.67E+09	1.91E+09	9/9 (100%)
<i>Staphylococcus aureus</i> ATCC 11632	1.48E+08 2.00E+07 2.56E+07	6.45E+07	9/9 (100%)	8.75E+08 9.80E+08 1.21E+08	6.59E+08	9/9 (100%)
<i>Staphylococcus aureus</i> [MRSA/mecA] ATCC BAA-1747	1.41E+07 5.65E+06 6.05E+06	8.60E+06	9/9 (100%)	5.70E+07 3.85E+07 9.75E+07	6.43E+07	9/9 (100%)
<i>Staphylococcus epidermidis</i> ATCC 12228	1.38E+08 9.85E+07 1.16E+08	1.18E+08	9/9 (100%)	2.12E+08 3.95E+08 1.56E+09	7.22E+08	9/9 (100%)
<i>Staphylococcus epidermidis</i> [MRSE/mecA]	3.60E+07 3.75E+07	7.65E+07	9/9 (100%)	1.35E+09 6.80E+08	1.44E+09	9/9 (100%)

Species/Isolate(s) Tested	At Positivity			8 Hours After Positivity		
	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)
ATCC 29887	1.56E+08			2.29E+09		
<i>Streptococcus agalactiae</i> ATCC 13813	4.50E+08 1.22E+08 9.15E+08	4.96E+08	9/9 (100%)	3.15E+08 5.80E+08 4.30E+08	4.42E+08	9/9 (100%)
<i>Streptococcus mitis</i> ATCC 15914	1.57E+08 1.51E+09 6.90E+08	7.86E+08	9/9 (100%)	1.50E+09 2.03E+09 2.91E+09	2.15E+09	9/9 (100%)
<i>Streptococcus pneumoniae</i> ATCC BAA-255	3.45E+08 2.67E+08 1.31E+09	6.41E+08	9/9 (100%)	1.03E+09 6.00E+08 1.37E+09	1.00E+09	9/9 (100%)
<i>Streptococcus pyogenes</i> ATCC 19615	2.53E+08 2.44E+08 3.80E+08	2.92E+08	9/9 (100%)	2.38E+08 5.70E+08 8.90E+08	5.66E+08	9/9 (100%)
Gram-Negative Bacteria						
<i>Acinetobacter baumannii</i> ATCC 9955	2.17E+08 1.44E+08 2.45E+08	2.02E+08	9/9 (100%)	4.85E+08 3.85E+08 4.35E+08	4.35E+08	9/9 (100%)
<i>Enterobacter cloacae</i> ATCC 13047	4.20E+08 3.95E+08 1.50E+08	3.22E+08	9/9 (100%)	2.23E+09 1.46E+09 2.19E+09	1.96E+09	9/9 (100%)
<i>Escherichia coli</i> ATCC 43888	9.80E+07 6.10E+07 1.93E+08	1.17E+08	9/9 (100%)	1.17E+09 1.39E+09 7.70E+07	8.79E+08	9/9 (100%)
<i>Klebsiella oxytoca</i> ATCC 13182	7.40E+08 6.85E+08 3.85E+08	6.03E+08	9/9 (100%)	3.05E+09 1.86E+09 1.20E+09	2.04E+09	9/9 (100%)
<i>Klebsiella oxytoca</i> [+KPC] JMI 7818	6.15E+07 9.15E+07 3.05E+07	6.12E+07	9/9 (100%)	1.96E+09 2.00E+09 1.13E+09	1.70E+09	9/9 (100%)
<i>Klebsiella pneumoniae</i> ATCC 13883	4.35E+08 2.10E+08 9.15E+08	5.20E+08	9/9 (100%)	1.60E+09 1.65E+09 1.58E+09	1.61E+09	9/9 (100%)
<i>Klebsiella pneumoniae</i> [+KPC] JMI 766	1.21E+08 2.50E+08 2.05E+08	1.92E+08	9/9 (100%)	1.14E+09 9.10E+08 7.70E+08	9.40E+08	9/9 (100%)
<i>Proteus mirabilis</i> ATCC 29906	3.25E+07 1.04E+08 9.10E+07	7.58E+07	9/9 (100%)	1.04E+09 9.80E+08 7.30E+08	9.17E+08	9/9 ^a (100%)
<i>Serratia marcescens</i> ATCC 27137	8.35E+08 1.46E+09 4.90E+08	9.28E+08	9/9 (100%)	1.05E+09 1.37E+09 1.02E+09	1.15E+09	9/9 (100%)
<i>Serratia marcescens</i> [+KPC] JMI 697	4.90E+08 3.90E+08 1.02E+08	3.27E+08	9/9 (100%)	2.19E+09 1.40E+09 2.42E+08	1.28E+09	9/9 (100%)
<i>Haemophilus influenzae</i> (type b) ATCC 10211	2.80E+08 3.60E+08 2.23E+08	2.88E+08	9/9 (100%)	3.25E+09 3.35E+09 2.74E+09	3.11E+09	9/9 (100%)
<i>Neisseria meningitidis</i> ATCC 43744	2.07E+08 3.90E+08 1.55E+08	2.51E+08	9/9 (100%)	6.65E+08 7.65E+08 7.85E+08	7.38E+08	9/9 (100%)
<i>Pseudomonas aeruginosa</i> ATCC 27853	1.34E+08 1.76E+08 9.75E+07	1.36E+08	9/9 (100%)	1.35E+09 1.39E+08 1.76E+09	1.08E+09	9/9 (100%)
Yeast						
<i>Candida albicans</i> ATCC 10231	9.05E+03 8.00E+04 4.65E+03	3.12E+04	9/9 (100%)	8.80E+04 1.03E+05 1.00E+05	9.70E+04	9/9 (100%)
<i>Candida glabrata</i> ATCC 15545	1.26E+06 1.11E+06	1.45E+06	9/9 (100%)	1.47E+07 2.65E+07	2.01E+07	9/9 (100%)

Species/Isolate(s) Tested	At Positivity			8 Hours After Positivity		
	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)
	1.97E+06			1.91E+07		
<i>Candida krusei</i> ATCC 90878	5.65E+06 2.47E+06 6.35E+06	4.82E+06	9/9 (100%)	2.68E+07 3.55E+07 3.25E+07	3.16E+07	9/9 (100%)
<i>Candida parapsilosis</i> ATCC 90875	2.56E+06 3.60E+06 3.20E+06	3.12E+06	9/9 (100%)	6.70E+07 3.80E+07 5.55E+07	5.35E+07	9/9 (100%)
<i>Candida tropicalis</i> ATCC 66029	1.50E+06 7.45E+05 6.65E+05	9.70E+05	9/9 (100%)	1.10E+07 2.04E+07 9.45E+06	1.36E+07	9/9 (100%)
Overall Correct Detection^a (Organism and Antimicrobial Resistance Genes)	At Positivity:		270/270 (100%)	8 Hours After Positivity:		270/270 (100%)

^a In addition to the correct results, 5 false positive results (*Streptococcus*, *Streptococcus agalactiae*, *Haemophilus influenzae*, *Neisseria meningitidis*, and *Candida krusei*) were observed in a single run (1/540; 0.2%). The correct results were obtained when the sample was retested.

Inclusivity

Analytical reactivity (inclusivity) of the BCID Panel was evaluated in a study that assessed the ability of the BCID Panel to detect a diverse collection of 303 isolates of genetically, phenotypically, and geographically diverse bacteria and yeast, and to properly indicate the presence of four different antimicrobial resistance genes.

Each isolate was initially tested in blood culture matrix at a concentration consistent with the levels of organism enumerated from blood cultures at the time of positivity (see Growth and Detection section above). If the expected result was obtained at the initial test level, no further testing was performed. If an isolate was not detected initially, additional testing was performed at 10-100 fold higher concentrations. If detected at the higher concentration(s), the species/isolate is indicated as detected with reduced sensitivity and the concentration of organism that was detected is indicated. If not detected at the highest concentration, the isolate is listed as not detected by the FilmArray BCID Panel. Results are provided below for each FilmArray BCID Panel test result.

When possible, *in silico* analysis of sequence data was used to make predictions of assay reactivity for less common species that may be detected by the FilmArray BCID Panel but were not tested.

Gram-Positive Bacteria

Enterococcus

Table 23. *Enterococcus* Inclusivity Results

<i>Enterococcus</i> Detected [~1x10 ⁸ CFU/mL]		<i>Enterococcus</i> Detected with Reduced Sensitivity [~1x10 ⁹ CFU/mL]		<i>Enterococcus</i> Not Detected ^a	
<i>Enterococcus avium</i>	ATCC 49463	<i>Enterococcus saccharolyticus</i>	ATCC 43076	<i>Enterococcus pseudoavium</i>	ATCC 49372
<i>Enterococcus casseliflavus</i>	ATCC 700668	<i>Enterococcus dispar</i>	ATCC 51266	<i>Enterococcus raffinosus</i>	ATCC 49427
<i>Enterococcus cecorum</i>	ATCC 43198				

<i>Enterococcus</i> Detected [~1x10 ⁸ CFU/mL]		<i>Enterococcus</i> Detected with Reduced Sensitivity [~1x10 ⁹ CFU/mL]	<i>Enterococcus</i> Not Detected ^a
<i>Enterococcus durans</i>	ATCC 11576		
<i>Enterococcus faecalis</i>	ATCC 49532		
	ATCC 49533		
	JMI 12536		
	ATCC 51299		
	ATCC 700802		
	JMI 368		
<i>Enterococcus faecium</i>	ATCC 27270		
	ATCC 35667		
	ATCC BAA-2127		
	JMI 536		
	ATCC 700221		
	JMI 475		
<i>Enterococcus flavescens</i>	ATCC 49996		
<i>Enterococcus gallinarum</i>	ATCC 49608		
<i>Enterococcus hirae</i>	ATCC 8043		
<i>Enterococcus malodoratus</i>	ATCC 43197		
<i>Enterococcus mundtii</i>	ATCC 43187		

^a Not detected at the highest test concentrations ~1x10⁹-1x10¹⁰ CFU/mL.

Listeria monocytogenes

Table 24. *Listeria monocytogenes* Inclusivity Results

<i>Listeria monocytogenes</i> Detected ^a		
Species	Serotype	Isolate ID
<i>Listeria monocytogenes</i>	1/2a	FSL-C1-056 ^b
<i>Listeria monocytogenes</i>	1/2a	FSL-J2-020 ^b
<i>Listeria monocytogenes</i>	1/2b	FSL-J2-064 ^b
<i>Listeria monocytogenes</i>	1/2b	HUM-2009042206 ^c
<i>Listeria monocytogenes</i>	4b	ATCC 43256
<i>Listeria monocytogenes</i>	4b	ATCC 13932

^a Estimated concentration in a positive blood culture is ~5x10⁸ CFU/mL.

^b Isolates obtained from Cornell University.

^c Isolates obtained from the Colorado Department of Public Health (CDPH).

Staphylococcus (including *Staphylococcus aureus*)

Table 25. *Staphylococcus aureus* Inclusivity Results

<i>Staphylococcus/Staphylococcus aureus</i> Detected ^a			
Species	Isolate ID	Strain Information	PFGE Type
Methicillin-sensitive <i>S. aureus</i> (MSSA)			

Staphylococcus/Staphylococcus aureus Detected^a			
Species	Isolate ID	Strain Information	PFGE Type
<i>Staphylococcus aureus</i>	ATCC BAA-1749	96:308	USA 900
<i>Staphylococcus aureus</i>	ATCC BAA-1759	N7129	USA 900
<i>Staphylococcus aureus</i>	ATCC BAA-1765	102-04	USA 1200
<i>Staphylococcus aureus</i> ^b	ATCC 12600	NCTC 8532 Type strain	Unknown
<i>Staphylococcus aureus</i> ^b	ATCC 11632	S13	Unknown
<i>Staphylococcus aureus</i>	ATCC BAA-2419	Mass/2010	Unknown
<i>Staphylococcus aureus</i>	ATCC BAA-2420	Mass/2010	Unknown
<i>Staphylococcus aureus</i>	ATCC BAA-2421	Mass/2010	Unknown
<i>Staphylococcus aureus</i>	1060728	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	Ant1	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	Lem8	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	MAL8134	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	MAQ	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	Per2	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	RAR	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	S313	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	Sal3	n/a ^c	Unknown
<i>Staphylococcus aureus</i>	Ver2	n/a ^c	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i> ^b	ATCC 10832	Wood 46	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i> ^b	ATCC 14154	Rose	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC 25923	Seattle/1945	Unknown
Borderline Oxacillin-resistant <i>S. aureus</i> (BORSA)			
<i>Staphylococcus aureus</i>	SUN1 ^d	n/a	Unknown
<i>Staphylococcus aureus</i>	SUN2 ^d	n/a	Unknown
<i>Staphylococcus aureus</i>	SUN3 ^d	n/a	Unknown
<i>Staphylococcus aureus</i>	SUN4 ^d	n/a	Unknown
<i>Staphylococcus aureus</i>	SUN5 ^d	n/a	Unknown
<i>Staphylococcus aureus</i>	SUN6 ^d	n/a	Unknown
Methicillin-resistant <i>S. aureus</i> (MRSA)			
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-38	E2125 Denmark	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC 43300	F-182 Kansas	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC 700698	Mu3 Japan/1996	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-1720	MRSA252 UK	Unknown
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-39	HUSA304 Hungary/1993	Unknown
<i>Staphylococcus aureus</i>	NARSA NRS705	NY-12 New York/2005	USA 100
<i>Staphylococcus aureus</i>	NARSA NRS701	MN-082 Minn/2006	USA 200
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-1717	TCH1516 Texas	USA 300
<i>Staphylococcus aureus</i>	NARSA NRS703	MN-095 Minn/2006	USA 300
<i>Staphylococcus aureus</i>	NARSA NRS683	GA-298 Georgia/2005	USA 300
<i>Staphylococcus aureus</i>	NARSA NRS662	CO-34 Colorado/2005	USA 300
<i>Staphylococcus aureus</i>	NARSA NRS707	NY-155 New York/2005	USA 300
<i>Staphylococcus aureus</i>	ATCC BAA-1707	MW2 N. Dakota/1998	USA 400
<i>Staphylococcus aureus</i>	NARSA NRS691	GA-62 Georgia/2005	USA 500
<i>Staphylococcus aureus</i>	NARSA NRS648	CA-347 California/2005	USA 600
<i>Staphylococcus aureus</i>	NARSA NRS689	GA-442 Georgia/2006	USA 700
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-42	HDE288 Portugal/1996	USA 800
<i>Staphylococcus aureus</i>	NARSA NRS668	CO-72 Colorado/2005	USA 800
<i>Staphylococcus aureus</i>	ATCC BAA-1747	94:1013 Vermont/1993	USA 1000
<i>Staphylococcus aureus</i>	NARSA NRS676	CT-19 Conn/2005	USA 1000
<i>Staphylococcus aureus</i>	NARSA NRS745	CA-629 California/2006	USA 1000
<i>Staphylococcus aureus</i>	ATCC BAA-1764	7031 Alaska	USA 1100
<i>Staphylococcus aureus</i>	ATCC BAA-1691	HFH-30137 Michigan/2003	Not 100-1100
<i>Staphylococcus aureus</i>	ATCC BAA-1700	HFH-33798 Illinois/2004	Not 100-1100
<i>Staphylococcus aureus</i>	ATCC BAA-2312	M10/0061 Ireland/2010	Unknown
<i>Staphylococcus aureus</i>	ATCC BAA-2313	M10/0148 Ireland/2010	CC130
<i>Staphylococcus aureus</i> (VRSA) ^e	NARSA VRS5	HIP15178 Michigan/2005	Unknown

^a Detected at the initial test concentration of 5x10⁶ CFU/mL.

^b Initial test concentration was 5×10^5 CFU/mL.

^c Isolates obtained from University of Rennes, France.

^d Isolates obtained from Sunnybrook Research Institute, affiliated with the University of Toronto.

^e Tested as a seeded blood culture at the time of positivity.

Table 26. Results of *Staphylococcus* (non-*S. aureus*) Inclusivity Testing^a

<i>Staphylococcus</i> Detected [~5x10 ⁶ CFU/mL]		<i>Staphylococcus</i> Detected with Reduced Sensitivity [~5x10 ⁷ CFU/mL]		<i>Staphylococcus</i> Not Detected ^b	
Coagulase-positive staphylococci (non- <i>S.aureus</i>)					
<i>Staphylococcus lutrae</i>	ATCC 700373			<i>Staphylococcus intermedius</i> ^c	ATCC 29663
				<i>Staphylococcus pseudointermedius</i>	ATCC 49444
				<i>Staphylococcus schleiferi</i> subsp. <i>coagulans</i>	ATCC 49545
Coagulase-negative staphylococci (CoNS)					
<i>Staphylococcus caprae</i>	ATCC 51548	<i>Staphylococcus capitis</i> subsp. <i>capitis</i>	ATCC 27842	<i>Staphylococcus auricularis</i>	Clinical isolate ^d
<i>Staphylococcus cohnii</i>	ATCC 29972	<i>Staphylococcus pasteurii</i>	ATCC 51127	<i>Staphylococcus carnosus</i>	ATCC 51365
<i>Staphylococcus epidermidis</i>	ATCC 12228	<i>Staphylococcus saprophyticus</i>	ATCC 15305	<i>Staphylococcus lentus</i> ^e	ATCC 700403
	ATCC 29886	<i>Staphylococcus simulans</i>	Clinical isolates ^f	<i>Staphylococcus pettenkoferi</i>	5 clinical isolates
	ATCC 55133	<i>Staphylococcus warneri</i>	ATCC 25614	<i>Staphylococcus schleiferi</i> subsp. <i>schleiferi</i>	ATCC 43808
	ATCC 29887			<i>Staphylococcus sciuri</i>	ATCC 29060
	ATCC 51625				
	ATCC 35984				
<i>Staphylococcus equorum</i>	ATCC 43958				
<i>Staphylococcus haemolyticus</i>	ATCC 29968				
<i>Staphylococcus hominis</i> <i>ssp. hominis</i>	ATCC 25615				
<i>Staphylococcus lugdunensis</i>	ATCC 43809				
<i>Staphylococcus xylosus</i>	ATCC 29966				

^a All 54 *S. aureus* isolates (Table 25 above) received *Staphylococcus* Detected results.

^b Not detected when tested at a concentration of $\geq 5 \times 10^8$ CFU/mL.

^c Isolates identified as *Staphylococcus intermedius* by automated identification systems were detected in two clinical specimens.

^d *Staphylococcus auricularis* was not tested in analytic studies, but was not detected in a clinical blood culture.

^e An isolate identified as *Staphylococcus lentus* by an automated identification system was detected in one clinical specimen.

^f *Staphylococcus simulans* was not tested in analytic studies, but was detected in three clinical blood cultures at unknown concentration.

Based on inclusivity testing results for *Staphylococci* and *in silico* analysis of available sequences, the following predictions of reactivity are provided for many less common CoNS species that were not tested.

Please note that performance of the FilmArray BCID Panel for these organisms has not been established.

Table 27. *In Silico* Predictions of *Staphylococcus* Reactivity

Detection Predicted ^a	Detection Predicted with Reduced Sensitivity ^b	Detection Not Predicted ^c
<i>Staphylococcus gallinarum</i>	<i>Staphylococcus microti</i>	<i>Staphylococcus arlettae</i>
<i>Staphylococcus kloosii</i>	<i>Staphylococcus simiae</i>	<i>Staphylococcus chromogenes</i>
	<i>Staphylococcus succinus</i>	<i>Staphylococcus condimenti</i>
		<i>Staphylococcus fleurettii</i>
		<i>Staphylococcus piscifermentans</i>
		<i>Staphylococcus pulvereri</i>
		<i>Staphylococcus rostri</i>
		<i>Staphylococcus saccharolyticus</i>
		<i>Staphylococcus vitulinus</i>

^a Predicted result of *Staphylococcus* Detected when present in a blood culture sample at a concentration of $\geq 5 \times 10^6$ CFU/mL.

^b Predicted result of *Staphylococcus* Detected when present in a blood culture sample at a concentration of $\geq 5 \times 10^7$ CFU/mL.

^c Predicted result of *Staphylococcus* Not Detected at relevant concentrations.

***Streptococcus* (including *S. agalactiae*, *S. pneumoniae*, and *S. pyogenes*)**

Table 28. *Streptococcus* Inclusivity Results

<i>Streptococcus</i> Detected ^a		
Species	Isolate ID	Strain Information
<i>Streptococcus pyogenes</i>	ATCC 19615	Group A (Pyogenic group)
<i>Streptococcus pyogenes</i>	PCMC 20100107CI02	
<i>Streptococcus pyogenes</i>	ATCC 49399	
<i>Streptococcus pyogenes</i>	ATCC 12344	
<i>Streptococcus pyogenes</i>	ATCC 12384	
<i>Streptococcus agalactiae</i>	ATCC 13813 Type strain – Serotype 1a/c	Group B (Pyogenic group)
<i>Streptococcus agalactiae</i>	PCMC 20100107CI03 Untyped clinical isolate	
<i>Streptococcus agalactiae</i>	ATCC 12403 Type III	
<i>Streptococcus agalactiae</i>	ATCC BAA-611 Serotype V	
<i>Streptococcus agalactiae</i>	NCTC 8017 Unknown serotype	
<i>Streptococcus dysgalactiae</i> ssp. <i>equisimilis</i>	ATCC 12388	Group C/G (Pyogenic group)
<i>Streptococcus bovis</i>	ATCC 33317	Group D (Bovis group)
<i>Streptococcus equinus</i>	ATCC 9812	
<i>Streptococcus mutans</i>	ATCC 25175	Group E (Mutans group)
<i>Streptococcus anginosus</i>	ATCC 33397	Group F (Anginosus group)
<i>Streptococcus intermedius</i>	ATCC 27335	
<i>Streptococcus constellatus</i>	ATCC 27513	
<i>Streptococcus gordonii</i>	ATCC 10558	Mitis group
<i>Streptococcus parasanguinis</i>	ATCC 31412	
<i>Streptococcus sanguinis</i>	ATCC 10556	
<i>Streptococcus mitis</i>	ATCC 15914	
<i>Streptococcus oralis</i>	ATCC 10557	
<i>Streptococcus pseudopneumoniae</i>	ATCC BAA-960	
<i>Streptococcus pneumoniae</i>	ATCC BAA-255 Strain R6 (no capsule)	
<i>Streptococcus pneumoniae</i>	ATCC 700672 Serotype 14	
<i>Streptococcus pneumoniae</i>	ATCC BAA-334	

<i>Streptococcus</i> Detected^a		
Species	Isolate ID	Strain Information
	Serotype 4	
<i>Streptococcus pneumoniae</i>	ATCC 700673	
	Serotype 19A	
<i>Streptococcus pneumoniae</i>	ATCC BAA-341	
	Serotype 5	
<i>Streptococcus salivarius</i>	ATCC 13419	Salivarius group
<i>Streptococcus gallolyticus</i>	ATCC BAA-2069	Uncertain grouping

^a Detected at the initial test concentration of $\sim 1 \times 10^8$ CFU/mL.

Table 29. *Streptococcus agalactiae* Inclusivity Results

<i>Streptococcus/Streptococcus agalactiae</i> (Group B) Detected^a		
Species	Isolate ID	Strain Information
<i>Streptococcus agalactiae</i>	ATCC 13813	Group B (Pyogenic group)
	Type strain – Serotype 1a/c	
<i>Streptococcus agalactiae</i>	PCMC 20100107CI03	
	Untyped clinical isolate	
<i>Streptococcus agalactiae</i>	ATCC 12403	
	Type III	
<i>Streptococcus agalactiae</i>	ATCC BAA-611	
	Serotype V	
<i>Streptococcus agalactiae</i>	NCTC 8017	
	Unknown serotype	

^a Detected at the initial test concentration of $\sim 1 \times 10^8$ CFU/mL.

Table 30. *Streptococcus pneumoniae* Inclusivity Results

<i>Streptococcus/Streptococcus pneumoniae</i> Detected^{a,b}		
Species	Isolate ID	Strain Information
<i>Streptococcus pneumoniae</i>	ATCC BAA-255	Mitis group
	Strain R6 (no capsule)	
<i>Streptococcus pneumoniae</i>	ATCC 700672	
	Serotype 14	
<i>Streptococcus pneumoniae</i>	ATCC BAA-334	
	Serotype 4	
<i>Streptococcus pneumoniae</i>	ATCC 700673	
	Serotype 19A	
<i>Streptococcus pneumoniae</i>	ATCC BAA-341	
	Serotype 5	

^a Detected at the initial test concentration of $\sim 1 \times 10^8$ CFU/mL.

^b Based on sequence analysis, the BCID Panel may not detect *S. pneumoniae* serotypes 11A and 19, or may detect these serotypes with reduced sensitivity compared to other serotypes.

Table 31. *Streptococcus pyogenes* Inclusivity Results

<i>Streptococcus/Streptococcus pyogenes</i> (Group A) Detected^a		
Species	Isolate ID	Strain Information
<i>Streptococcus pyogenes</i>	ATCC 19615	Group A (Pyogenic group)
<i>Streptococcus pyogenes</i>	PCMC 20100107CI02	
<i>Streptococcus pyogenes</i>	ATCC 49399	
<i>Streptococcus pyogenes</i>	ATCC 12344	
<i>Streptococcus pyogenes</i>	ATCC 12384	

^a Detected at the initial test concentration of $\sim 1 \times 10^8$ CFU/mL.

Based on results of inclusivity testing and *in silico* analysis of available sequences, the following predictions of reactivity are provided for less common *Streptococcus* species that were not tested. As shown in Table 32 below, the analysis predicts that many species

will be detected at concentrations expected in positive blood cultures (10^8 - 10^9 CFU/mL), and others (particularly Mutans group species) will likely not be detected due to sequence mismatches with the assay primers.

Please note that performance of the FilmArray BCID Panel for these organisms has not been established.

Table 32. *In Silico* Predictions of *Streptococcus* Reactivity

Detection Predicted ^a	Detection Predicted with Reduced Sensitivity ^b	Detection Not Predicted
<i>Streptococcus australis</i>	<i>Streptococcus parauberis</i>	<i>Streptococcus criceti</i> ^c
<i>Streptococcus equi</i>		<i>Streptococcus downei</i> ^c
<i>Streptococcus ictaluri</i>		<i>Streptococcus macacae</i> ^c
<i>Streptococcus infantis</i>		<i>Streptococcus porcinus</i>
<i>Streptococcus infantarius</i>		<i>Streptococcus urialis</i>
<i>Streptococcus pasteurianus</i>		
<i>Streptococcus peroris</i>		
<i>Streptococcus suis</i>		
<i>Streptococcus thermophilus</i>		
<i>Streptococcus vestibularis</i>		

^a Predicted result of *Streptococcus* Detected when present in a blood culture sample at a concentration of $\sim 1 \times 10^8$ CFU/mL.

^b Predicted result of *Streptococcus* Detected when present in a blood culture sample at a concentration of $\geq 1 \times 10^9$ CFU/mL.

^c Mutans group streptococci.

Gram-Negative Bacteria

Acinetobacter baumannii

Table 33. *Acinetobacter baumannii* Inclusivity Results

<i>Acinetobacter baumannii</i> Detected ^a	
Species	Isolate ID
<i>Acinetobacter baumannii</i>	ATCC 9955
<i>Acinetobacter baumannii</i>	ATCC BAA-1605
<i>Acinetobacter baumannii</i>	ATCC 17961
<i>Acinetobacter baumannii</i>	ATCC 19003
<i>Acinetobacter baumannii</i>	ATCC BAA-2093
<i>Acinetobacter baumannii</i>	ATCC 15308

^a Detected at the initial test concentration of $\sim 1 \times 10^8$ CFU/mL.

***Enterobacteriaceae* (including *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus*, and *Serratia marcescens*)**

Table 34. Results of *Enterobacteriaceae* Inclusivity Testing

<i>Enterobacteriaceae</i> Detected [$\sim 5 \times 10^7$ CFU/mL or 1×10^8 CFU/mL]		<i>Enterobacteriaceae</i> Detected with Reduced Sensitivity [$\sim 5 \times 10^8$ - 1×10^9 CFU/mL]		<i>Enterobacteriaceae</i> Not Detected ^a	
<i>Cedeceae davisiæ</i>	ATCC 43023	<i>Edwardsiella tarda</i>	ATCC 15947	<i>Morganella morganii</i> subsp. <i>morganii</i>	ATCC 25829
<i>Citrobacter freundii</i>	ATCC 43864	<i>Enterobacter gergoviae</i>	ATCC 33028	<i>Pantoea</i> (<i>Enterobacter</i>) <i>agglomerans</i> ^b	ATCC 27155
<i>Citrobacter koseri</i>	ATCC 29223	<i>Hafnia alvei</i>	ATCC 51815	<i>Providencia</i> (<i>Proteus</i>) <i>uocalifaciens</i>	ATCC 51902
<i>Cronobacter muytjensii</i>	ATCC 51329	<i>Salmonella bongori</i>	SGSC 3041	<i>Providencia</i> (<i>Proteus</i>) <i>rettgeri</i>	ATCC 9250

Enterobacteriaceae Detected [~5×10 ⁷ CFU/mL or 1×10 ⁸ CFU/mL]		Enterobacteriaceae Detected with Reduced Sensitivity [~5×10 ⁸ -1×10 ⁹ CFU/mL]		Enterobacteriaceae Not Detected ^a	
<i>Cronobacter (Enterobacter) sakazakii</i>	ATCC 29544	<i>Serratia fonticola</i>	ATCC 29844	<i>Providencia stuarti</i>	ATCC 33672
<i>Enterobacter aerogenes</i>	ATCC 13048	<i>Serratia odorifera</i>	ATCC 33077	<i>Rahnella aquatilis</i>	ATCC 33071
<i>Enterobacter aerogenes</i>	ATCC 29751	<i>Serratia rubidua</i>	ATCC 27593	<i>Serratia liquefaciens</i>	ATCC 27592
<i>Enterobacter asburiae</i>	ATCC 35953			<i>Tatumella tyseos</i>	ATCC 33301
<i>Enterobacter amnigenus</i>	ATCC 51816			<i>Serratia plymuthica</i>	ATCC 183
<i>Enterobacter cloacae</i>	9 isolates ^c			<i>Yersinia enterocolitica</i>	ATCC 6025
<i>Enterobacter hormaechei</i>	ATCC 49162				
<i>Enterobacter kobei</i>	ATCC BAA-260 ^d				
<i>Enterobacter nimipressuralis</i>	ATCC 9912 ^d				
<i>Escherichia coli</i>	5 isolates ^e				
<i>Escherichia fergusonii</i>	ATCC 35469				
<i>Escherichia hermanii</i>	ATCC 33650				
<i>Escherichia vulneris</i>	ATCC 33821				
<i>Klebsiella oxytoca</i>	11 isolates ^f				
<i>Klebsiella pneumoniae</i>	10 isolates ^g				
<i>Klebsiella variicola</i>	ATCC BAA-830				
<i>Kluyvera ascorbata</i>	ATCC 33433				
<i>Kluyvera (Enterobacter) intermedius</i>	ATCC 33110				
<i>Leclercia adecarboxylata</i>	ATCC 23216				
<i>Proteus species</i>	10 isolates ^h				
<i>Raoultella ornithinolytica</i>	ATCC 31898				
<i>Raoultella planticola</i>	ATCC 31900				
<i>Raoultella terrigena</i>	ATCC 33257				
<i>Salmonella enterica-cholerae</i>	ATCC 10708				
<i>Salmonella enterica-heidelberg</i>	ATCC 8326				
<i>Salmonella enterica-paratyphi</i>	SGSC 3222				
<i>Salmonella enterica-typhimurium</i>	ATCC 13311				
<i>Serratia marcescens</i>	6 isolates ⁱ				
<i>Serratia entomophila</i>	ATCC 43705				
<i>Serratia ficaria</i>	ATCC 33105				
<i>Shigella boydii</i> ^j	ATCC 8700				
<i>Shigella dysenteriae</i> ^j	PHM-2004008089				
<i>Shigella flexneri</i> ^j	ATCC 12022				
<i>Shigella sonnei</i> ^j	ATCC 11060				
<i>Yokenella regensburgei</i>	ATCC 35313				

^a Not Detected at the highest test concentration of 1×10⁹-1×10¹⁰ CFU/mL.

^b Not Detected in this study, but *Pantoea agglomerans* was detected by the BCID Panel in a clinical blood culture.

^c See *Enterobacter cloacae* complex table.

^d Tested as purified nucleic acid at a concentration of 0.63µg/mL (equivalent to ~1.0×10⁸ CFU/mL).

^c See *Escherichia coli* table.

^f See *Klebsiella oxytoca* table.

^g See *Klebsiella pneumoniae* table.

^h See *Proteus* table.

ⁱ See *Serratia marcescens* table.

^j Tested as a seeded blood culture within 1 hour of positivity.

Based on results of inclusivity testing and *in silico* analysis of available sequences, the following predictions of reactivity are provided for less common *Enterobacteriaceae* that were not tested.

Please note that performance of the FilmArray BCID Panel for these organisms has not been established.

Table 35. *In silico* Predictions of *Enterobacteriaceae* Reactivity

Detection Predicted with Reduced Sensitivity ^a	Detection Not Predicted	Unknown Reactivity ^b
<i>Brenneria</i> spp.	<i>Photorhabdus</i> spp.	<i>Buttiauxella</i> spp.
<i>Dickeya</i> spp.	<i>Serratia grimesii</i>	<i>Ewingella americana</i>
<i>Erwinia</i> spp.	<i>Serratia proteamaculans</i>	<i>Leminorella</i> spp.
<i>Pectobacterium</i> spp.	<i>Xenorhabdus</i> spp.	<i>Moellerella</i> spp.
	<i>Yersinia</i> spp.	

^a Predicted result of *Enterobacteriaceae* Detected when present in a blood culture sample at a concentration of $\geq 1 \times 10^8$ CFU/mL

^b Sequence data not available for *in silico* reactivity predictions.

Enterobacter cloacae complex

Table 36. Summary of *Enterobacter cloacae* complex Inclusivity Results

<i>Enterobacter cloacae</i> complex Detected [$\sim 1 \times 10^8$ CFU/mL]		<i>Enterobacter cloacae</i> complex Not Detected ^a	
<i>Enterobacter asburiae</i>	ATCC 35953	<i>Enterobacter nimipressuralis</i> ^b	ATCC 9912
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i>	ATCC BAA-1143	<i>Enterobacter kobei</i>	ATCC BAA-260
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i>	ATCC 13047		
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i>	NCTC 10005		
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i>	ATCC 49141		
<i>Enterobacter cloacae</i> subsp. <i>dissolvens</i> ^b	ATCC 23373		
<i>Enterobacter hormaechei</i>	ATCC 49162		

^a Not Detected at highest test concentration of 1×10^{10} CFU/mL.

^b Tested as purified nucleic acid at a concentration of 0.63 µg/mL (equivalent to $\sim 1 \times 10^8$ CFU/mL). Detected by *Enterobacteriaceae* assay.

Escherichia coli

Table 37. *Escherichia coli* Inclusivity Results

<i>Escherichia coli</i> Detected ^a		
Species	Isolate ID	Strain Info
<i>Escherichia coli</i>	ATCC 43888	CDC B6914-MS1 serotype O157:H7
<i>Escherichia coli</i>	ATCC 49105	7482-1-1 serotype O15
<i>Escherichia coli</i>	ATCC 25922	FDA-Seattle1946

<i>Escherichia coli</i>	ATCC 35401	H10407 serotype O78:H11
<i>Escherichia coli</i>	ATCC BAA-201	Produces ESB� TEM-3

^a Detected at the initial test concentration of 5×10^7 CFU/mL.

Klebsiella oxytoca

Table 38. *Klebsiella oxytoca* Inclusivity Results

<i>Klebsiella oxytoca</i> Detected ^a			<i>Klebsiella oxytoca</i> Not Detected ^b		
Species	Isolate ID	Strain Info	Species	Isolate ID	Strain Info
<i>Klebsiella oxytoca</i>	ATCC 13182	n/a	<i>Klebsiella oxytoca</i> ^{b,c}	JMI 10678	MY/2011
<i>Klebsiella oxytoca</i>	ATCC 49131	n/a			
<i>Klebsiella oxytoca</i>	ATCC 700324	n/a			
<i>Klebsiella oxytoca</i>	ATCC 43086	n/a			
<i>Klebsiella oxytoca</i>	ATCC 8724	n/a			
<i>Klebsiella oxytoca</i>	JMI 14611	AR/2011			
<i>Klebsiella oxytoca</i>	JMI 12707	MA/2011			
<i>Klebsiella oxytoca</i>	JMI 7818	AR/2004			
<i>Klebsiella oxytoca</i>	JMI 2661	NY/2003			
<i>Klebsiella oxytoca</i>	JMI 2523	n/a			

^a Detected at the initial test concentration of 5×10^7 CFU/mL.

^b Detected as *Enterobacteriaceae* at the initial test concentration of 5×10^7 CFU/mL but Not Detected for *Klebsiella oxytoca* at the highest test concentration of 1×10^{10} CFU/mL.

^c Sequence analysis confirmed this isolate as a variant *K. oxytoca* that will not be detected by the FilmArray BCID Panel Koxytoca assay.

Klebsiella pneumoniae

Table 39. *Klebsiella pneumoniae* Inclusivity Results

<i>Klebsiella pneumoniae</i> Detected ^a		
Species	Isolate ID	Strain Information
<i>Klebsiella pneumoniae</i>	ATCC BAA-1706	n/a
<i>Klebsiella pneumoniae</i> ssp. <i>pneumoniae</i>	ATCC 13883	Type strain
<i>Klebsiella pneumoniae</i> ssp. <i>ozaenae</i>	ATCC 11296	NCTC 5050
<i>Klebsiella pneumoniae</i> ssp. <i>rhinoscleromatis</i>	ATCC 13884	NCTC 5046 Type strain
<i>Klebsiella pneumoniae</i>	ATCC 700603	n/a
<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	n/a
<i>Klebsiella pneumoniae</i>	JMI 766	n/a
<i>Klebsiella pneumoniae</i>	JMI 328	n/a
<i>Klebsiella pneumoniae</i>	JMI 8091	n/a
<i>Klebsiella pneumoniae</i>	JMI 438	n/a
<i>Klebsiella variicola</i> ^b	ATCC BAA-830	F2R9/ 2001 Type strain

^a Detected at the initial test concentration of 1×10^8 CFU/mL.

^b Identical sequence to *K. pneumoniae* variant 342. Both *K. pneumoniae* variant 342 and *Klebsiella variicola* have been recovered from clinical specimens and will be identified by the BCID Panel and most phenotypic laboratory methods as *Klebsiella pneumoniae*.

Proteus

Table 40. *Proteus* Inclusivity Results

<i>Proteus</i> Detected ^a	
Species	Isolate ID
<i>Proteus mirabilis</i>	ATCC 29906
	JMI 10793
	ATCC 25933
	ATCC 33583
	ATCC 7002
<i>Proteus hauseri</i>	ATCC 13315

	ATCC 700826
<i>Proteus penneri</i>	ATCC 33519
<i>Proteus vulgaris</i>	ATCC 33420
	ATCC 27973

^a Detected at the initial test concentration of 1×10^7 CFU/mL.

Serratia marcescens

Table 41. *Serratia marcescens* Inclusivity Results

<i>Serratia marcescens</i> Detected ^a		
Species	Isolate ID	Strain Information
<i>Serratia marcescens</i>	ATCC 13880	Type strain
<i>Serratia marcescens</i>	ATCC 14756	n/a
<i>Serratia marcescens</i>	ATCC 27137	n/a
<i>Serratia marcescens</i>	ATCC 43297	n/a
<i>Serratia marcescens</i>	JMI 697	CT/2009
<i>Serratia marcescens</i>	JMI 8089	TX/2004

^a Detected at the initial test concentration of 1×10^8 CFU/mL.

Haemophilus influenzae

Table 42. *Haemophilus influenzae* Inclusivity Results

<i>Haemophilus influenzae</i> Detected ^a		
Species	Isolate ID	Strain Information
<i>Haemophilus influenzae</i>	ATCC 33929	Non-typeable
<i>Haemophilus influenzae</i>	ATCC 51907	Non-typeable
<i>Haemophilus influenzae</i> ssp. <i>aegyptus</i>	ATCC 11116	Non-typeable
<i>Haemophilus influenzae</i>	ATCC 9006	Type a
<i>Haemophilus influenzae</i>	ATCC 31512	Type b
<i>Haemophilus influenzae</i>	ATCC 10211	Type b
<i>Haemophilus influenzae</i>	ATCC 49699	Type c
<i>Haemophilus influenzae</i>	ATCC 9008	Type d
<i>Haemophilus influenzae</i>	ATCC 8142	Type e
<i>Haemophilus influenzae</i>	ATCC 700223	Type f

^a Detected in a positive blood culture tested within 1 hour of positivity. The concentration of *H. influenzae* in a positive blood culture at the time of positivity is estimated to be $\sim 1 \times 10^8$ CFU/mL.

Neisseria meningitidis (encapsulated)

Table 43. *Neisseria meningitidis* Inclusivity Results

<i>Neisseria meningitidis</i> Detected ^a			<i>Neisseria meningitidis</i> Not Detected ^b		
Species	Isolate ID	Serogroup	Species	Isolate ID	Serogroup
<i>Neisseria meningitidis</i>	ATCC 43744	W135	<i>Neisseria meningitidis</i> (unencapsulated)	Clinical isolate ^c	None
<i>Neisseria meningitidis</i>	ATCC 13077	A	<i>Neisseria meningitidis</i> (unencapsulated)	Clinical isolate ^c	None
<i>Neisseria meningitidis</i>	ATCC 13090	B	<i>Neisseria meningitidis</i> (unencapsulated)	Clinical isolate ^c	None
<i>Neisseria meningitidis</i>	ATCC 13102	C	<i>Neisseria meningitidis</i>	Clinical isolate ^c	None

<i>Neisseria meningitidis</i> Detected ^a			<i>Neisseria meningitidis</i> Not Detected ^b		
Species	Isolate ID	Serogroup	Species	Isolate ID	Serogroup
<i>Neisseria meningitidis</i>	ATCC 13113	D	(unencapsulated)		
<i>Neisseria meningitidis</i>	ATCC 35561	Y	<i>Neisseria meningitidis</i>	Clinical isolate ^c	B

^a Detected in a seeded blood culture tested within 1 hour of positivity (estimated concentration $\sim 1 \times 10^8$ CFU/mL).

^b Not Detected in a seeded blood culture tested 1-5 hours after positivity.

^c Clinical isolates of unencapsulated *N. meningitidis* were tested from seeded positive blood cultures to confirm that they would not be detected by the BCID Panel.

^d DNA from a clinical isolate with a variant *ctrA* gene was tested and not detected at a concentration equivalent to 2.5×10^9 CFU/mL. DNA obtained from University of Lausanne, Institute of Microbiology, Switzerland.

Pseudomonas aeruginosa

Table 44. *Pseudomonas aeruginosa* Inclusivity Results

<i>Pseudomonas aeruginosa</i> Detected ^a	
Species	Isolate ID
<i>Pseudomonas aeruginosa</i>	ATCC 27853
<i>Pseudomonas aeruginosa</i>	ATCC 10145
<i>Pseudomonas aeruginosa</i>	ATCC 19429
<i>Pseudomonas aeruginosa</i>	ATCC 25619
<i>Pseudomonas aeruginosa</i>	ATCC BAA-1744
<i>Pseudomonas aeruginosa</i>	ATCC 35554

^a Detected at the initial test concentration of 1×10^8 CFU/mL.

Yeast

Candida albicans

Table 45. Results of *Candida albicans* Inclusivity Testing

<i>Candida albicans</i> Detected ^a		
Species	Isolate ID	Strain Info
<i>Candida albicans</i>	ATCC 10231	Serotype A - 3147
<i>Candida albicans</i>	ATCC MYA-427	A39 [DUMC 136.97]
<i>Candida albicans</i>	ATCC MYA-2876	SC5314
<i>Candida albicans</i>	ATCC 11651	171D
<i>Candida albicans</i>	ATCC 22972	M 97
<i>Candida albicans</i>	ATCC 90028	NCCLS 11

^a Detected at the initial test concentration of 1×10^4 CFU/mL.

Candida glabrata

Table 46. Results of *Candida glabrata* Inclusivity Testing

<i>Candida glabrata</i> Detected ^a		
Species	Isolate ID	Strain Info
<i>Candida glabrata</i>	ATCC 15545	NRRL YB-4025
<i>Candida glabrata</i>	ATCC 32554	26247-1
<i>Candida glabrata</i>	ATCC 2001	CBS138
<i>Candida glabrata</i>	ATCC 15126	CBS15126
<i>Candida glabrata</i>	ATCC MYA-2950	n/a

^a Detected at the initial test concentration of 1×10^6 CFU/mL.

Candida krusei

Table 47. Results of *Candida krusei* Inclusivity Testing

<i>Candida krusei</i> Detected ^a		
Species	Isolate ID	Strain Info
<i>Candida krusei</i>	ATCC 90878	B74
<i>Candida krusei</i>	ATCC 201748	89-08-008
<i>Candida krusei</i>	ATCC 14243	n/a
<i>Candida krusei/Issatchenkia orientalis</i> ^b	ATCC 28870	CBS 2052
<i>Issatchenkia orientalis</i> ^b	ATCC 6258	NRRL Y-413

^a Detected at the initial test concentration of 1×10^6 CFU/mL.

^b *Issatchenkia orientalis* and *Pichia kudriavzevii* are anamorphs of *C. krusei*.

Candida parapsilosis

Table 48. Results of *Candida parapsilosis* Inclusivity Testing

<i>Candida parapsilosis</i> Detected ^a			<i>Candida parapsilosis</i> Detected with Reduced Sensitivity ^b		
Species	Isolate ID	Strain Info	Species	Isolate ID	Strain Info
<i>Candida parapsilosis</i>	ATCC 90875	B78	<i>Candida parapsilosis</i>	ATCC 96142	MCO462 [UTHSC R-648]
<i>Candida parapsilosis</i>	ATCC 34136	ST-89			
<i>Candida parapsilosis</i>	ATCC 96138	MCO433			
<i>Candida parapsilosis</i>	ATCC 22019	CBS604			

^a Detected at the initial test concentration of 1×10^6 CFU/mL.

^b Detected at a test concentration of 1×10^7 CFU/mL.

Candida tropicalis

Table 49. Results of *Candida tropicalis* Inclusivity Testing

<i>Candida tropicalis</i> Detected ^a		
Species	Isolate ID	Strain Info
<i>Candida tropicalis</i>	ATCC 66029	AmMS 227
<i>Candida tropicalis</i>	ATCC 750	Type Strain
<i>Candida tropicalis</i>	ATCC 90874	B79
<i>Candida tropicalis</i>	ATCC MYA-2734	508-12.1
<i>Candida tropicalis</i> ^b	ATCC 201380	API 90 01 105 (Vitek QC)

^a Detected at the initial test concentration of 1×10^5 CFU/mL.

^b Target concentration was 5×10^5 CFU/mL, final test concentration was 1×10^6 CFU/mL (2×).

Antimicrobial Resistance Genes

mecA

Table 50. *mecA* Inclusivity Results

<i>mecA</i> Detected ^{a,b}			
Species	Isolate ID	Strain Information	SCC _{mec} Type
Methicillin-sensitive <i>S. aureus</i> (MSSA) with SCC _{mec} cassette (<i>mecA</i> positive)			
<i>Staphylococcus aureus</i>	ATCC BAA-2419	Mass/2010	II

<i>mecA</i> Detected ^{a,b}			
Species	Isolate ID	Strain Information	SCCmec Type
<i>Staphylococcus aureus</i>	ATCC BAA-2420	Mass/2010	II
<i>Staphylococcus aureus</i>	ATCC BAA-2421	Mass/2010	II
Methicillin-resistant <i>S. epidermidis</i> (MRSE) (<i>mecA</i> positive)			
<i>Staphylococcus epidermidis</i>	ATCC 29887	255-01B	Unknown
<i>Staphylococcus epidermidis</i> ^c	ATCC 51625	CCF 15990	
<i>Staphylococcus epidermidis</i>	ATCC 35984	RP62A	
Methicillin-resistant <i>S. aureus</i> (MRSA) (<i>mecA</i> positive)			
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-38	E2125 Denmark	I
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC 43300	F-182 Kansas	II
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC 700698	Mu3 Japan/1996	II
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-1720	MRSA252 UK	II
<i>Staphylococcus aureus</i>	NARSA NRS705	NY-12 New York/2005	II
<i>Staphylococcus aureus</i>	NARSA NRS701	MN-082 Minn/2006	II
<i>Staphylococcus aureus</i>	NARSA NRS648	CA-347 California/2005	II
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-39	HUSA304 Hungary/1993	III 3A&5
<i>Staphylococcus aureus</i>	NARSA NRS703	MN-095 Minnesota/2006	IV
<i>Staphylococcus aureus</i>	NARSA NRS683	GA-298 Georgia/2005	IV
<i>Staphylococcus aureus</i>	NARSA NRS662	CO-34 Colorado/2005	IV
<i>Staphylococcus aureus</i>	NARSA NRS707	NY-155 New York/2005	IV
<i>Staphylococcus aureus</i>	ATCC BAA-1707	MW2 N. Dakota/1998	IV
<i>Staphylococcus aureus</i>	NARSA NRS691	GA-62 Georgia/2005	IV
<i>Staphylococcus aureus</i>	NARSA NRS689	GA-442 Georgia/2006	IV
<i>Staphylococcus aureus</i>	NARSA NRS668	CO-72 Colorado/2005	IV
<i>Staphylococcus aureus</i>	ATCC BAA-1747	94:1013 Vermont/1993	IV
<i>Staphylococcus aureus</i>	NARSA NRS676	CT-19 Conn/2005	IV
<i>Staphylococcus aureus</i>	ATCC BAA-1764	7031 Alaska	IV
<i>Staphylococcus aureus</i>	ATCC BAA-1691	HFH-30137 Michigan/2003	IV
<i>Staphylococcus aureus</i>	ATCC BAA-1700	HFH-33798 Illinois/2004	IV
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-1717	TCH1516 Texas	IVa
<i>Staphylococcus aureus</i>	NARSA NRS745	CA-629 California/2006	V
<i>Staphylococcus aureus</i> ssp. <i>aureus</i>	ATCC BAA-42	HDE288 Portugal/1996	VI
Methicillin-resistant <i>S. aureus</i> with <i>mecA</i> _{1GA251} / <i>mecC</i> variant			
<i>Staphylococcus aureus</i>	ATCC BAA-2312	M10/0061 Ireland/2010	XI
<i>Staphylococcus aureus</i>	ATCC BAA-2313	M10/0148 Ireland/2010	XI

^a Detected at the initial test concentration of 5×10^6 CFU/mL.

^b *Staphylococcus* Detected and/or *Staphylococcus aureus* Detected results also reported, as appropriate.

^c Initial test concentration was 5×10^3 CFU/mL.

vanA/B

Table 51. *vanA/B* Inclusivity Results

<i>vanA/B</i> Detected^{a,b}		
Species	Isolate ID	Strain Information
<i>Enterococcus faecium</i> [<i>vanA</i>]	JMI 536	TX/2006
<i>Enterococcus faecium</i> [<i>vanA</i>]	ATCC 700221	Connecticut
<i>Enterococcus faecium</i> [<i>vanA</i>]	JMI 475	IN/2003
<i>Enterococcus faecalis</i> [<i>vanA</i>]	JMI 12536	Mass/2002

vanA/B Detected ^{a,b}		
Species	Isolate ID	Strain Information
<i>Enterococcus faecalis</i> [vanB]	ATCC 51299	Missouri
<i>Enterococcus faecalis</i> [vanB]	ATCC 700802	Missouri/1987
<i>Enterococcus faecalis</i> [vanB]	JMI 368	VA/2003

^a Detected at the initial test concentration of 1×10^8 CFU/mL.

^b *Enterococcus* Detected results also reported.

KPC

Table 52. KPC Inclusivity Results

KPC Detected ^{a,b}			
Species ^c	Isolate ID	KPC Type	Strain Information
<i>Enterobacter cloacae</i>	BAA-2341	Unknown	1101152
<i>Enterobacter hormaechei</i>	BAA-2082	Unknown	n/a
<i>Escherichia coli</i>	BAA-2340	Unknown	1101362
<i>Klebsiella oxytoca</i>	JMI 2523	Unknown	n/a
<i>Escherichia coli</i>	Clinical Isolate	KPC-2	n/a
<i>Enterobacter cloacae</i>	Clinical Isolate	KPC-2	n/a
<i>Klebsiella oxytoca</i>	JMI 7818	KPC-2	AR/2004
<i>Klebsiella pneumoniae</i>	JMI 328	KPC-2	n/a
<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	KPC-2	Modified Hodge Test Control
<i>Serratia marcescens</i>	JMI 697	KPC-2	CT/2009
<i>Enterobacter cloacae</i>	Clinical Isolate	KPC-3	n/a
<i>Klebsiella oxytoca</i>	JMI 2661	KPC-3	NY/2003
<i>Klebsiella pneumoniae</i>	JMI 766	KPC-4	n/a
<i>Klebsiella pneumoniae</i>	JMI 8091	KPC-4	n/a
<i>Klebsiella pneumoniae</i>	JMI 438	KPC-4	n/a

^a Detected at the initial test concentration of 5×10^7 CFU/mL for *K. oxytoca* isolates and 1×10^8 CFU/mL for *K. pneumoniae* and *S. marcescens* isolates. Detected in a seeded blood culture tested within 1 hour of positivity for *Enterobacter* spp. and *E. coli*.

^b *Enterobacteriaceae* and corresponding species specific Detected results also reported.

^c Other isolates which carry the KPC gene (i.e. *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacteriaceae* other than those listed above) were not evaluated.

Exclusivity

The potential for cross-reactivity with BCID Panel assays was evaluated by testing high concentrations of organism in contrived or seeded blood culture samples. The test concentration was equal to or greater than the level of organism estimated to be in a blood culture sample 8 hours after positivity (approximately 10^9 - 10^{10} CFU/mL for bacteria and 10^7 - 10^8 CFU/mL for yeast), or the highest concentration possible based on the organism stock. The selection of organisms focused on species that may be found in positive blood cultures (clinically relevant) and/or those that are closely related to target organisms (nearest neighbors). Organisms were also selected based on antimicrobial resistance phenotypes and the presence or absence of the antimicrobial resistance genes identified by the BCID Panel. The tested organisms were divided into two categories: on-panel organisms and off-panel organisms.

On-panel organisms were tested to verify that they only react with the appropriate assays on the panel. On-panel exclusivity testing included gram-positive bacteria, gram-negative bacteria and yeast, representing 29 genera and 98 individual species.

Off-panel organisms were expected to have negative test results for all of the assays on the FilmArray BCID Panel (or positive organism results but negative results for the

antimicrobial resistance genes detected by the FilmArray BCID Panel). Off-panel testing included gram-positive bacteria, gram-negative bacteria, yeast, viruses, and *Mycoplasmataceae*.

Results are presented for all organisms that were tested and received the expected FilmArray BCID Panel test result(s) (no cross-reactivity, Tables 53 - 57), followed by a summary of species or isolates with which cross-reactivity was observed (Table 59).

Table 53. Non-Cross-Reactive Gram Positive Bacteria

ON PANEL			
<i>Enterococcus</i> Species	<i>Staphylococcus aureus</i>	Coagulase-Negative Staphylococci	<i>Streptococcus</i> Species
<i>E. avium</i> <i>E. casseliflavus</i> (2 isolates) <i>E. cecorum</i> <i>E. dispar</i> <i>E. durans</i> <i>E. faecalis</i> (3 isolates) <i>E. faecium</i> (2 isolates) ^a <i>E. gallinarium</i> (2 isolates) <i>E. hirae</i> <i>E. raffinosus</i>	MSSA (18 isolates) Resistant <i>S. aureus</i> – BORSA (6 isolates) MRSA (<i>mecA</i>) VRSA (<i>mecA</i> , <i>vanA</i>)	<i>S. capitis</i> ssp. <i>capitis</i> <i>S. caprae</i> <i>S. cohnii</i> <i>S. epidermidis</i> (2 isolates) <i>S. haemolyticus</i> <i>S. hominis</i> <i>S. lugdunensis</i> <i>S. pasteurii</i> <i>S. saprophyticus</i> <i>S. schleiferi</i> ssp. <i>schleiferi</i> <i>S. sciuri</i> <i>S. warneri</i> <i>S. xylosum</i>	<i>S. agalactiae</i> <i>S. anginosus</i> <i>S. bovis</i> <i>S. dysgalactiae</i> <i>S. gallolyticus</i> <i>S. mitis</i> <i>S. mutans</i> <i>S. parasanguinis</i> <i>S. pneumoniae</i> <i>S. pseudopneumoniae</i> <i>S. pyogenes</i> <i>S. salivarius</i>
<i>Listeria monocytogenes</i>	Coagulase-Positive Staphylococci <i>S. intermedius</i> <i>S. lutrae</i> <i>S. pseudointermedius</i> <i>S. schleiferi</i> ssp. <i>coagulans</i>		
<i>L. monocytogenes</i>			
OFF PANEL			
Gram-positive Cocci	Gram-positive Bacilli	<i>Listeria</i> Species	Gram-positive Anaerobes
<i>Granulicatella adiacens</i> ^b <i>Gemella morbillorum</i> <i>Lactococcus lactis</i> <i>Macrococcus caseolyticus</i> <i>Micrococcus luteus</i> <i>Vagococcus fluvialis</i>	<i>Actinomyces odontolyticus</i> <i>Bacillus cereus</i> <i>Corynebacterium jeikeium</i> <i>Lactobacillus acidophilus</i> <i>Mycobacterium tuberculosis</i> ^c <i>Rhodococcus equi</i> <i>Rothia mucilaginosa</i>	<i>L. (murrayi) grayi</i> <i>L. innocua</i> ^d <i>L. ivanovii</i> ssp. <i>londoniensis</i> <i>L. seeligeri</i> <i>L. welshimeri</i>	<i>Clostridium perfringens</i> <i>Peptostreptococcus anaerobius</i> <i>Propionibacterium acnes</i>

Abbreviations: BORSA=Borderline-oxacillin resistant *Staphylococcus aureus*; MRSA=Methicillin Resistant *Staphylococcus aureus*; VRSA=Vancomycin Resistant *Staphylococcus aureus*.

^a One isolate was tested at a concentration of 5ng/mL Extracted DNA; ~1×10⁶ CFU/mL.

^b A false positive *Streptococcus* result was observed in the initial test of this isolate. The expected negative results were observed in multiple subsequent tests. No cross-reactivity between *G. adiacens* and the BCID Panel *Streptococcus* assays is predicted by sequence analysis.

^c Tested at a concentration of 7.33×10⁶ CFU/mL.

^d *In silico* analysis predicts that cross-reactivity between the *L. monocytogenes* assay and some atypical strains of *L. innocua* is possible, however, no cross-reactivity was observed in this testing.

NOTE: While not observed in this study, cross-reactivity between the *Enterococcus* assay and some *Staphylococcus* species may occur when the staphylococci are present in a sample at very high concentrations.

Table 54. Non-Cross-Reactive Gram Negative Bacteria

ON PANEL			
<i>Acinetobacter baumannii</i>	Enterobacteriaceae Isolates^a		
<i>A. baumannii</i> (2 isolates)	<i>Cedeceae davisiae</i>	<i>Escherichia hermanii</i>	<i>Providencia acalifaciens</i>
<i>Haemophilus influenzae</i>	<i>Citrobacter fruendi</i>	<i>Escherichia vulneris</i>	<i>Providencia rettgeri</i>
	<i>Citrobacter koseri</i>	<i>Hafnia alvei</i>	<i>Providencia stuarti</i>
<i>H. influenzae</i> (type b)	<i>Cronobacter muytjensi</i>	<i>Klebsiella oxytoca</i> (3 isolates)	<i>Rahnella aquatilis</i>
	<i>Cronobacter sakazakii</i>	<i>Klebsiella pneumoniae</i> (6 isolates)	<i>Raoultella terrigena</i>
<i>Neisseria meningitidis</i>	<i>Enterobacter amnigenus</i>	<i>Klebsiella pneumoniae</i> (6 isolates)	<i>Raoultella planticola</i>
	<i>Enterobacter asburiae</i>	<i>Kluyvera ascorbata</i>	<i>Salmonella enterica</i>
<i>N. meningitidis</i>	<i>Enterobacter cancerogenus</i>	<i>Kluyvera intermedius</i>	<i>Serratia liquefaciens</i>
	<i>Enterobacter cloacae</i>	<i>Leclercia</i>	<i>Serratia fonticola</i>
<i>Pseudomonas aeruginosa</i>	<i>Enterobacter hormaechei</i>	<i>adecarboxylata</i>	<i>Serratia marcescens</i> (2 isolates)
	<i>Enterobacter gergoviae</i>	<i>Morganella morganii</i>	<i>Serratia plymuthica</i>
<i>P. aeruginosa</i>	<i>Escherichia coli</i> (2 isolates)	<i>Pantoea agglomerans^b</i>	<i>Tatumella pyseos</i>
		<i>Proteus mirabilis</i>	<i>Yersinia enterocolitica</i>
		<i>Proteus penneri</i>	<i>Yokenella regensburgi</i>
		<i>Proteus vulgaris</i>	
OFF PANEL			
<i>Acinetobacter</i> Species	<i>Haemophilus</i> Species	<i>Pseudomonas</i> Species	Gram-negative Bacilli
<i>A. calcoaceticus</i>	<i>H. parahaemolyticus</i>	<i>P. fluorescens</i>	<i>Aeromonas hydrophila</i>
<i>A. haemolyticus</i>	<i>H. parainfluenzae</i>	<i>P. luteola</i>	<i>Brevundimonas</i>
<i>A. johnsonii</i>	<i>H. parasuis</i>	<i>P. nitroreducens</i>	<i>diminuta</i>
<i>A. junii</i>	<i>H. somnus</i>	<i>P. oryzae</i>	<i>Moraxella catarrhalis</i>
<i>A. lwoffii</i>	<i>Neisseria</i> Species	<i>P. pertucinogena</i>	(3 isolates)
<i>A. radioresistens</i>		<i>P. stutzeri</i>	<i>Stenotrophomonas</i>
<i>A. schindleri</i>	<i>N. sicca</i>	Gram-negative Anaerobes	<i>maltophilia</i>
<i>A. ursingii</i>	<i>N. elongate</i>		<i>Vibrio parahaemolyticus</i>
<i>A. nosocomialis</i> (genomospecies 13TU; 2 isolates)	<i>N. perflava</i>	<i>Bacteroides fragilis</i>	<i>Bordetella pertussis</i>
	<i>N. mucosa</i>	<i>Veillonella parvula</i>	<i>Campylobacter fetus</i>
	<i>N. lactamica</i>		<i>Chlamydia trachomatis</i>
			<i>Legionella pneumophila^c</i>

^a Some isolates were not detected by the FilmArray BCID Panel and are discussed in the inclusivity evaluation.

^b *In silico* analysis indicates that cross-reactivity between the *Enterobacter cloacae* complex assay and *Pantoea* (*Enterobacter*) *agglomerans* may be possible. However, no cross-reactivity was observed in this study.

^c Tested at a concentration of 2.63×10^8 CFU/mL.

Table 55. Non-Cross-Reactive Fungi

ON PANEL	OFF PANEL	
<i>Candida</i> Species	<i>Candida</i> Species	Non- <i>Candida</i> Fungi
<i>C. albicans</i>	<i>C. dubliniensis</i>	<i>Aspergillus fumigatus</i>
<i>C. glabrata</i>	<i>C. lusitaniae</i>	<i>Debaryomyces hansenii</i>
<i>C. krusei</i>	<i>C. metapsilosis</i>	<i>Kluyveromyces lactis</i>
<i>C. parapsilosis</i>	<i>C. multigemmis^a</i>	<i>Saccharomyces cerevisiae</i>
<i>C. tropicalis</i>		<i>Schizosaccharomyces pombe</i>

^a *In silico* analysis predicts that cross-reactivity between the Cparapsilosis assay and *C. multigenim* is possible, however, no cross-reactivity was observed in this testing.

Table 56. Non-Cross-Reactive Viruses and *Mycoplasmataceae*

OFF PANEL	
<i>Mycoplasmataceae</i> Isolates	Viruses
<i>Mycoplasma hominis</i> (3.16×10 ⁷ CFU/mL)	Cytomegalovirus (1.67×10 ⁴ TCID ₅₀ /mL)
<i>Ureaplasma urealyticum</i> (1.57×10 ⁶ CFU/mL)	Epstein Barr Virus (1.00×10 ⁵ TCID ₅₀ /mL)
	Herpes Simplex Virus - Type 1 (1:30 dilution of stock)
	Varicella Zoster Virus (8.17×10 ³ TCID ₅₀ /mL)

Table 57. Non-Cross-Reactive Antimicrobial Resistance

ON PANEL		OFF PANEL ^a	
<i>mecA</i>			
Methicillin Resistant Staphylococci (<i>mecA</i>)		Borderline Oxacillin Resistant <i>S. aureus</i> (BORSA)	
<i>Staphylococcus epidermidis</i> -MRSE	<i>mecA</i>	<i>Staphylococcus aureus</i> -BORSA (6 isolates)	
<i>Staphylococcus aureus</i> -MRSA	<i>mecA</i>	Methicillin Sensitive Staphylococci	
<i>Staphylococcus aureus</i> -VRSA	<i>mecA/vanA</i>	<i>Staphylococcus aureus</i> -MSSA (18 isolates) ^b	
		<i>Staphylococcus epidermidis</i> -MRSE (1 isolate)	
		<i>Staphylococcus</i> spp. (16 isolates)	
<i>vanA/B</i>			
Vancomycin Resistant Enterococci (<i>vanA/B</i>)		Vancomycin Resistant Enterococci (non-<i>vanA/B</i>)	
<i>Enterococcus faecalis</i>	<i>vanB</i>	<i>Enterococcus casseliflavus</i>	<i>vanC</i>
<i>Enterococcus faecium</i>	<i>vanA</i>	<i>Enterococcus casseliflavus</i>	<i>vanC</i>
		<i>Enterococcus gallinarum</i>	<i>vanC</i>
		<i>Enterococcus gallinarum</i>	<i>vanC</i>
		Vancomycin Sensitive Enterococci	
		<i>Enterococcus</i> spp. (8 isolates)	
KPC			
Carbapenem Resistant <i>Enterobacteriaceae</i> (KPC)		Carbapenem Resistant <i>Enterobacteriaceae</i> (non-KPC)	
<i>Klebsiella oxytoca</i>	KPC-2	<i>Klebsiella pneumoniae</i>	Unknown
<i>Klebsiella pneumoniae</i>	KPC-4	<i>Klebsiella pneumoniae</i>	NDM
<i>Serratia marcescens</i>	KPC-2	Carbapenem Sensitive/Beta-lactam Resistant Isolates	
		<i>Klebsiella pneumoniae</i>	AmpC
		<i>Klebsiella pneumoniae</i>	SHV
		<i>Escherichia coli</i>	TEM-3/CTX-1
		<i>Acinetobacter baumannii</i>	<i>bla</i> OXA
		<i>Moraxella catarrhalis</i>	<i>bla</i> OXA
		<i>Moraxella catarrhalis</i>	BRO-1(<i>bla</i>)/ <i>orf3</i>
		Carbapenem Sensitive Isolates	
		<i>Enterobacteriaceae</i> (51 isolates)	
		<i>Acinetobacter baumannii</i> (1 isolate)	
		<i>Pseudomonas aeruginosa</i> (2 isolates)	

^a Off-panel refers to the antimicrobial resistance gene. Organisms may be positive for organism assay(s).

^b Ten of the 18 isolates are known to harbor remnants of SCC_{mec} cassette.

Table 58. Predicted and Observed Cross-Reactivity Between BCID Panel Assays and On-Panel or Off-Panel Organisms Tested for Exclusivity

BCID Panel Assay/Result	Cross-Reactive Organism(s)/Isolate(s)/Gene
Gram-positive Bacteria	
<i>Enterococcus</i>	Some coagulase-negative staphylococci ^a
Gram-negative Bacteria	
<i>Acinetobacter baumannii</i>	<i>Acinetobacter calcoaceticus-baumannii</i> (ACB) complex species: <i>Acinetobacter calcoaceticus</i> (ssp. <i>anitratus</i>) ^b <i>Acinetobacter pittii</i> (formerly <i>genomospecies 3</i>) ^b
<i>Escherichia coli</i> / <i>Enterobacteriaceae</i>	<i>Shigella</i> species: <i>Shigella boydii</i> <i>Shigella dysenteriae</i> <i>Shigella flexneri</i> <i>Shigella sonnei</i> <i>Escherichia fergusonii</i>
<i>Klebsiella pneumoniae</i> / <i>Enterobacteriaceae</i>	<i>Klebsiella variicola</i> (or <i>Klebsiella pneumoniae</i> variant 342) <i>Enterobacter aerogenes</i> <i>Raoultella ornithinolytica</i> ^c
<i>Serratia marcescens</i> / <i>Enterobacteriaceae</i>	<i>Serratia</i> species (<i>Serratia entomophila</i> ^c , <i>Serratia ficaria</i> , <i>Serratia odorifera</i> ^d , <i>Serratia rubidaea</i> ^d) <i>Raoultella ornithinolytica</i> ^c <i>Pseudomonas aeruginosa</i> (ATCC 25619) ^f <i>Pseudomonas putida</i> ^e
<i>Haemophilus influenzae</i>	<i>Haemophilus haemolyticus</i> ^g
Yeast	
<i>Candida parapsilosis</i>	<i>Candida orthopsilosis</i> (Group III <i>Candida parapsilosis</i>) ^h
Antimicrobial Resistance Genes	
<i>vanA/B</i>	<i>vanM</i> ⁱ

^a Cross-reactivity was not observed in this study but is predicted by *in silico* analysis to occur only with some species (i.e. *S. epidermidis*, *S. capitis* and *S. haemolyticus*) when present in a sample at very high levels. This cross-reactivity was observed infrequently in pre-analytical studies and the clinical evaluation (estimated occurrence of ~0.2% of all prospective patient samples).

^b *Acinetobacter calcoaceticus-baumannii* (ACB) complex species are often mis-identified as *A. baumannii* by automated and manual microbial identification methods.

^c Cross-reactivity was not observed when ATCC 31898 was tested in the inclusivity study at a concentration ~1x10⁸ CFU/mL, but cross-reactivity was observed in clinical cultures containing *R. ornithinolytica*.

^d Cross-reactivity was observed only at high organism concentration (≥10⁹ CFU/mL); rare human pathogens.

^e *Pseudomonas putida* is a rare opportunistic pathogen.

^f No cross-reactivity observed with five other *Pseudomonas aeruginosa* isolates tested at ≥10⁸ CFU/mL.

^g *Haemophilus haemolyticus* is a commensal organism of the respiratory tract that is rarely isolated from blood culture.

^h *Candida orthopsilosis* is mis-identified as *C. parapsilosis* by automated and manual microbial identification methods.

ⁱ Vancomycin-resistant *Enterococcus faecium* isolated in Asia, 2011; *vanB* resistance phenotype.

Reproducibility

A multicenter reproducibility study was performed to determine between-site and overall reproducibility of the BCID Panel. Reproducibility testing occurred at three test sites using a panel of six simulated blood culture specimens, each spiked with various

combinations of two different organisms (analytes). To best represent the composition of specimens likely to be tested by the BCID Panel, half of the analytes were at a concentration consistent with the level of organism in a blood culture bottle at the time of positivity, and half of the analytes were at a concentration similar to that observed in bottles eight hours after positivity (see Growth and Detection above). Negative results for each assay were obtained from samples that were not spiked with a corresponding organism (analyte not in the sample).

The data incorporate a range of potential variation introduced by seven different operators, three different pouch lots, and ten different FilmArray Instruments. Every specimen was tested on eight different days, for a total of 90 replicates per analyte. A summary of results (percent (%) agreement with the expected result) for each analyte is provided in the following tables.

Table 59. Summary of Reproducibility Results – Organism Assays

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
<i>Enterococcus</i>	<i>Enterococcus faecium</i> [vanA] JMI475 1.50E+08 CFU/mL	Site A	30/30	0/30	180/180 100% [98.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	<i>Enterococcus faecalis</i> [vanB] JMI 368 8.95E+08 CFU/mL	Site A	30/30	0/30	
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/120	120/120	360/360 100% [99.0% - 100%]
		Site B	0/120	120/120	
		Site C	0/120	120/120	
		All Sites	0/360	360/360	
<i>Listeria monocytogenes</i>	Negative	Site A	0/180	180/180	540/540 100% [99.3% - 100%]
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	0/540	540/540	
<i>Staphylococcus</i>	<i>Staphylococcus aureus</i> [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	449/450* 99.8% [98.8% - 100%]
		Site B	1/150*	149/150	
		Site C	0/150	150/150	
		All Sites	1/450	449/450	
<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i> [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Streptococcus</i>	<i>Streptococcus pyogenes</i> ATCC 19615 5.70E+08 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Streptococcus agalactiae</i>	Negative	Site A	0/180	180/180	540/540 100% [99.3% - 100%]
		Site B	0/180	180/180	
		Site C	0/180	180/180	

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
<i>Streptococcus pneumoniae</i>	Negative	All Sites	0/540	540/540	540/540 100% [99.3% - 100%]
		Site A	0/180	180/180	
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	0/540	540/540	
<i>Streptococcus pyogenes</i>	<i>Streptococcus pyogenes</i> ATCC 19615 5.70E+08 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Acinetobacter baumannii</i>	<i>Acinetobacter baumannii</i> ATCC 9955 2.00E+08 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Enterobacteriaceae</i>	<i>Klebsiella pneumoniae</i> [KPC] JMI 766 9.40E+08 CFU/mL	Site A	30/30	0/30	180/180 100% [98.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	<i>Proteus mirabilis</i> ATCC 29906 9.20E+08 CFU/mL	Site A	30/30	0/30	360/360 100% [99.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/120	120/120	360/360 100% [99.0% - 100%]
		Site B	0/120	120/120	
		Site C	0/120	120/120	
		All Sites	0/360	360/360	
<i>Enterobacter cloacae</i> complex	Negative	Site A	0/180	180/180	540/540 100% [99.3% - 100%]
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	0/540	540/540	
<i>Escherichia coli</i>	Negative	Site A	0/180	180/180	540/540 100% [99.3% - 100%]
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	0/540	540/540	
<i>Klebsiella oxytoca</i>	Negative	Site A	0/180	180/180	540/540 100% [99.3% - 100%]
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	0/540	540/540	
<i>Klebsiella pneumoniae</i>	<i>Klebsiella pneumoniae</i> [KPC] JMI 766 9.40E+08 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Proteus</i>	<i>Proteus mirabilis</i> ATCC 29906 9.20E+08 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Serratia marcescens</i>	Negative	Site A	0/180	180/180	540/540 100%
		Site B	0/180	180/180	

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
		Site C	0/180	180/180	[99.3% - 100%]
		All Sites	0/540	540/540	
<i>Haemophilus influenzae</i>	Negative	Site A	0/180	180/180	539/540 ^a 98.0% [99.0% - 100%]
		Site B	1/180 ^a	179/180	
		Site C	0/180	180/180	
		All Sites	1/540	539/540	
<i>Neisseria meningitidis</i>	Negative	Site A	0/180	180/180	540/540 100% [99.3% - 100%]
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	0/540	540/540	
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i> ATCC 27853 1.40E+08 CFU/mL	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Candida albicans</i>	<i>Candida albicans</i> ATCC 10231 3.10E+04	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Candida glabrata</i>	<i>Candida glabrata</i> ATCC 15545 2.00E+07	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Candida krusei</i>	<i>Candida krusei</i> ATCC 90878 3.20E+07	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	
<i>Candida parapsilosis</i>	Negative	Site A	0/180	180/180	539/540 ^a 99.8% [99.0% - 100%]
		Site B	1/180 ^a	179/180	
		Site C	0/180	180/180	
		All Sites	1/540	539/540	
<i>Candida tropicalis</i>	<i>Candida tropicalis</i> ATCC 66029 9.70E+05	Site A	30/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	90/90	0/90	
	Negative	Site A	0/150	150/150	450/450 100% [99.2% - 100%]
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	0/450	450/450	

^a A single pouch run at Site B generated four false positive results: *Staphylococcus*, *mecA* (see below), *Haemophilus influenzae*, and *Candida parapsilosis*.

Table 60. Summary of Reproducibility Results – Antimicrobial Resistance Gene Assays

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results			% Agreement with Expected Test Result
			Detected	Not Detected	N/A	
<i>vanA/B</i>	<i>Enterococcus faecium</i> [<i>vanA</i>]	Site A	30/30	0/30	0/30	180/180

	JMI475 1.50E+08 CFU/mL	Site B	30/30	0/30	0/30	100% [98.0% - 100%]
		Site C	30/30	0/30	0/30	
		All Sites	90/90	0/90	0/90	
	<i>Enterococcus faecalis</i> [vanB] JMI 368 8.95E+08 CFU/mL	Site A	30/30	0/30	0/30	
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	
		All Sites	90/90	0/90	0/90	
	No Associated Organism	Site A	0/120	0/120	120/120	360/360 100% [99.0% - 100%]
		Site B	0/120	0/120	120/120	
		Site C	0/120	0/120	120/120	
		All Sites	0/360	0/360	360/360	
mecA	<i>Staphylococcus aureus</i> [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	30/30	0/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	
		All Sites	90/90	0/90	0/90	
	No Associated Organism	Site A	0/150	0/150	150/150	449/450 ^a 99.8% [98.8% - 100%]
		Site B	1/150 ^a	0/150	149/150	
		Site C	0/150	0/150	150/150	
		All Sites	1/450	0/450	449/450	
KPC	<i>Klebsiella pneumoniae</i> [KPC] JMI 766 9.40E+08	Site A	30/30	0/30	0/30	90/90 100% [96.0% - 100%]
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	
		All Sites	90/90	0/90	0/90	
	<i>Proteus mirabilis</i> ATCC 29906 and <i>Pseudomonas aeruginosa</i> ATCC 27853	Site A	0/90	90/90	0/90	270/270 100% [98.6% - 100%]
		Site B	0/90	90/90	0/90	
		Site C	0/90	90/90	0/90	
		All Sites	0/270	270/270	0/270	
	No Associated Organism	Site A	0/60	0/60	60/60	180/180 100% [98.0% - 100%]
		Site B	0/60	0/60	60/60	
		Site C	0/60	0/60	60/60	
		All Sites	0/180	0/180	180/180	

^a A single pouch run at Site B generated a false positive *mecA* result.

The reproducibility of Tm for each analyte and positive assay was also evaluated and a summary is provided in the following tables.

Table 61. Summary of Tm Analysis for Positive Organism Assays

BCID Panel Assay	Organism Tested Test Concentration	Test Site	Reproducibility of Tm				
			Tm Mean	Tm Std Dev	Tm Min	Tm Max	Range (max-min)
Gram-Positive Bacteria							
Enterococcus	<i>Enterococcus faecium</i> [vanA] JMI475 1.50E+08 CFU/mL	Site A	82.5	0.4	81.9	84.0	2.1
		Site B	82.6	0.2	82.3	83.0	0.7
		Site C	82.3	0.2	81.9	82.8	0.9
		All Sites	82.5	0.3	81.9	84.0	2.1
	<i>Enterococcus faecalis</i> [vanB] JMI 368 8.95E+08 CFU/mL	Site A	82.0	0.3	81.5	82.4	0.9
		Site B	82.2	0.2	81.8	82.8	1.0
		Site C	81.6	0.4	81.0	82.4	1.4
		All Sites	81.9	0.4	81.0	82.8	1.8
Saureus	<i>Staphylococcus aureus</i> [MRSA]	Site A	77.1	0.3	76.6	77.8	1.2

BCID Panel Assay	Organism Tested Test Concentration	Test Site	Reproducibility of Tm				
			Tm Mean	Tm Std Dev	Tm Min	Tm Max	Range (max-min)
	ATCC BAA-1747 8.60E+06 CFU/mL	Site B	77.3	0.3	76.8	77.8	1.0
		Site C	76.9	0.2	76.5	77.5	1.0
		All Sites	77.1	0.3	76.5	77.8	1.3
Streptococcus	<i>Streptococcus pyogenes</i> ATCC 19615 5.70E+08 CFU/mL	Site A	81.9	0.4	81.5	83.6	2.1
		Site B	82.1	0.1	81.8	82.3	0.5
		Site C	81.8	0.2	81.5	82.1	0.6
		All Sites	81.9	0.3	81.5	83.6	2.1
Spyogenes	<i>Streptococcus pyogenes</i> ATCC 19615 5.70E+08 CFU/mL	Site A	79.0	0.4	78.5	79.8	1.3
		Site B	79.2	0.3	78.7	79.8	1.1
		Site C	78.8	0.3	78.5	79.5	1.0
		All Sites	79.0	0.3	78.5	79.8	1.3
Gram-Negative Bacteria							
Abaumannii	<i>Acinetobacter baumannii</i> ATCC 9955 2.00E+08 CFU/mL	Site A	80.6	0.4	80.0	81.2	1.2
		Site B	80.8	0.2	80.4	81.2	0.8
		Site C	80.3	0.4	79.5	80.9	1.4
		All Sites	80.5	0.4	79.5	81.2	1.7
Enteric	<i>Klebsiella pneumoniae</i> [KPC] JMI 766 9.40E+08 CFU/mL	Site A	88.6	0.3	88.1	89.1	1.0
		Site B	88.8	0.1	88.6	89.2	0.5
		Site C	88.3	0.3	87.8	88.8	1.0
		All Sites	88.6	0.3	87.8	89.2	1.4
Kpneumoniae	<i>Klebsiella pneumoniae</i> [KPC] JMI 766 9.40E+08 CFU/mL	Site A	87.9	0.3	87.3	88.5	1.2
		Site B	88.1	0.2	87.8	88.4	0.6
		Site C	87.6	0.3	86.7	88.1	1.5
		All Sites	87.8	0.4	86.7	88.5	1.8
Proteus	<i>Proteus mirabilis</i> ATCC 29906 9.20E+08 CFU/mL	Site A	81.2	0.3	80.6	81.8	1.2
		Site B	81.4	0.2	81.2	81.9	0.7
		Site C	81.2	0.2	80.7	81.6	0.9
		All Sites	81.3	0.3	80.6	81.9	1.2
Pacuginosa	<i>Pseudomonas aeruginosa</i> ATCC 27853 1.40E+08 CFU/mL	Site A	87.9	0.3	87.3	88.5	1.2
		Site B	88.2	0.3	87.8	89.5	1.7
		Site C	88.5	0.2	88.1	89.1	1.0
		All Sites	88.2	0.4	87.3	89.5	2.2
Yeast							
Calbicans	<i>Candida albicans</i> ATCC 10231 3.10E+04	Site A	79.8	0.3	79.3	80.3	1.0
		Site B	80.1	0.2	79.7	80.5	0.8
		Site C	79.5	0.3	78.9	80.2	1.3
		All Sites	79.8	0.4	78.9	80.5	1.7
Cglabrata	<i>Candida glabrata</i> ATCC 15545 2.00E+07	Site A	75.3	0.3	74.7	76.1	1.3
		Site B	75.4	0.3	74.9	76.4	1.5
		Site C	75.7	0.2	75.4	76.1	0.7
		All Sites	75.5	0.3	74.7	76.4	1.7
Ckrusei	<i>Candida krusei</i> ATCC 90878 3.20E+07	Site A	84.5	0.4	84.1	85.2	1.2
		Site B	84.7	0.3	84.3	85.3	1.1
		Site C	85.0	0.3	84.6	85.8	1.3
		All Sites	84.8	0.4	84.1	85.8	1.8
Ctropicalis	<i>Candida tropicalis</i> ATCC 66029 9.70E+05	Site A	79.1	0.3	78.6	80.1	1.6
		Site B	79.2	0.2	78.8	79.6	0.8
		Site C	79.5	0.2	79.3	80.0	0.7

BCID Panel Assay	Organism Tested Test Concentration	Test Site	Reproducibility of T _m				
			T _m Mean	T _m Std Dev	T _m Min	T _m Max	Range (max-min)
		All Sites	79.3	0.3	78.6	80.1	1.6

Table 62. Summary of T_m Analysis for Positive Antimicrobial Resistance Gene Assays

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Reproducibility of T _m				
			T _m Mean	T _m Std Dev	T _m Min	T _m Max	Range (max-min)
<i>vanA/B</i>	<i>Enterococcus faecium</i> [<i>vanA</i>] JMI475 1.50E+08 CFU/mL	Site A	85.7	0.4	85.1	86.7	1.6
		Site B	86.0	0.3	85.5	86.5	1.0
		Site C	85.6	0.3	85.1	86.3	1.2
		All Sites	85.7	0.4	85.1	86.7	1.6
	<i>Enterococcus faecalis</i> [<i>vanB</i>] JMI 368 8.95E+08 CFU/mL	Site A	86.0	0.3	85.3	86.6	1.3
		Site B	86.3	0.2	85.9	86.9	1.0
		Site C	85.7	0.4	85.1	86.6	1.5
		All Sites	86.0	0.4	85.1	86.9	1.8
<i>mecA</i>	<i>Staphylococcus aureus</i> [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	73.6	0.3	73.1	74.4	1.3
		Site B	73.7	0.3	73.2	74.2	1.0
		Site C	73.4	0.3	72.8	74.1	1.3
		All Sites	73.6	0.3	72.8	74.4	1.7
KPC	<i>Klebsiella pneumoniae</i> [KPC] JMI 766 9.40E+08	Site A	86.2	0.3	85.5	86.7	1.1
		Site B	86.4	0.2	86.1	86.7	0.5
		Site C	85.9	0.3	85.2	86.4	1.2
		All Sites	86.1	0.4	85.2	86.7	1.5

Interference

Substances that could be present in blood culture samples or introduced during sample handling were evaluated for their potential to interfere with assay performance. A potentially interfering substance (see Table 63) was added to a simulated positive aerobic blood culture sample which contained simulated blood culture matrix (human whole blood that had been incubated in a blood culture bottle) and one of six different organism mixes. Each organism mix contained two live pathogens at a concentration equivalent to the level determined to be present when a blood culture bottle is detected as positive by the blood culture instrument. None of the substances tested were found to compete or interfere with the assays in the BCID Panel.

Table 63. Potentially Interfering Substances

Endogenous Substances	Exogenous Substances		Technique-Specific Substances
Hemoglobin Triglycerides Bilirubin γ-globulin Human Genomic DNA	Fluconazole Vancomycin Ciprofloxacin Gentamicin sulfate Imipenem	Ceftriaxone Tetracycline Amoxicillin/Clavulanate Heparin Sodium Polyanetholesulfonate (SPS)	Bleach Ethanol
On-Panel Competing Microorganisms		Off-Panel Competing Microorganisms	

<i>Staphylococcus epidermidis</i>	<i>Corynebacterium jeikeium</i>
<i>Escherichia coli</i>	<i>Bacillus cereus</i>
<i>Streptococcus mitis</i>	<i>Micrococcus luteus</i>
	<i>Clostridium perfringens</i>
	<i>Propionibacterium acnes</i>
Blood Culture Media/Bottle Types	
BACTEC Plus Aerobic/F	BacT/ALERT SA Standard Aerobic
BACTEC Standard Aerobic	BacT/ALERT SN Standard Anaerobic
BACTEC Standard Anaerobic	BacT/ALERT FA Aerobic FAN
BACTEC Plus Anaerobic/F	BacT/ALERT FN Anaerobic FAN
BACTEC Pediatric Plus	BacT/ALERT PF Pediatric FAN
BACTEC Lytic/10 Anaerobic/F	BacT/Alert FA Plus Aerobic
	VersaTREK REDOX 1
	VersaTREK REDOX 2

Note: While not shown to interfere in this evaluation, the BacT/ALERT blood culture bottles that contain charcoal have the potential to generate false positive results presumably due to the presence of nucleic acids from non-viable organisms and are listed as contraindicated for use with the FilmArray BCID Panel.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

BETH LINGENFELTER, M.S.
BIOFIRE DIAGNOSTICS, INC.
390 WAKARA WAY
SALT LAKE CITY UT 84108

June 21 2013

Re: K130914

Trade/Device Name: FilmArray Blood Culture Identification Panel

Regulation Number: 21 CFR 866.3365

Regulation Name: Multiplex Nucleic Acid Assay for Identification of Microorganisms and
Resistance Markers from Positive Blood Cultures

Regulatory Class: II

Product Code: PAM, PEO, PEN, OOI

Dated: March 30, 2013

Received: April 02, 2013

Dear Ms. Lingenfelter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, Ph.D., M.Sc
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130914

Device Name: FilmArray Blood Culture Identification (BCID) Panel

The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with the FilmArray Instrument. The FilmArray BCID Panel is capable of simultaneous detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance. The BCID assay is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as determined by Gram stain.

The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the FilmArray BCID Panel: *Enterococci*, *Listeria monocytogenes*, commonly encountered *Staphylococci* (including specific differentiation of *Staphylococcus aureus*), commonly encountered *Streptococci* (with specific differentiation of *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*), *Acinetobacter baumannii*, commonly encountered *Enterobacteriaceae* (including specific differentiation of the *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus*, and *Serratia marcescens*), *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*.

The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (*mecA*), vancomycin (*vanA* and *vanB*), and carbapenems (*bla_{KPC}*) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and carbapenems exist.

FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings. Positive FilmArray results do not rule out co-infection with organisms not included in the FilmArray BCID Panel. FilmArray BCID is not intended to monitor treatment for bacteremia or fungemia.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the FilmArray BCID Panel, and for species determination of some *Staphylococci*, *Enterococci*, *Streptococci*, and *Enterobacteriaceae* that are not specifically identified by the FilmArray BCID Panel assays.

Prescription Use x
(Part 21 CFR 801 Subpart D)

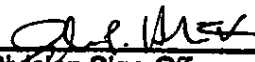
AND/OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

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ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health
(OIR)

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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
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